## Academic Organizing Partners

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WOMEN'S CANCER INITIATIVE
TATA MEMORIAL HOSPITAL

Nag Foundation
CANCER-CARE TO CURE

# 6th YEAR IN REVIEW
# BREAST CANCER

The year that was...2020

Click on Resource Center inside the virtual arena to see the meeting proceedings of
11th Jan to 15th Jan
**www.yearinreview.in/yir2021/login**

## Saturday, 16th Jan 2021

**Watch Live Meeting**

Practice Impacting Panel discussions
& International speakers Keynote
9.00am to 3.00pm

**www.yearinreview.in/yir2021/login**

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Please post your questions from 11th - 15th Jan which will be discussed on 16th Jan by the panel

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

## 11th - 16th JAN 2021

**Dear Colleagues,**

**Women's Cancer Initiative - Tata Memorial Hospital and Nag Foundation invite you for the "6th Edition of Year in Review: Breast Cancer Conference". This conference will be held virtually from 11th Jan to 15th Jan and presentations will be released at 9.00am daily and you can watch them throughout the day at your leisure. Keynote presentation and panel discussions will be live on Saturday from 9.00am to 3.00pm.**

The pandemic in 2020 has slowed down research, inspite of this many clinical, translational and basic science studies were published this year. Data presented at the YIR conference, are chosen from major breast cancer meetings and noteworthy publications from peer reviewed journals, likely to make an impact on our daily clinical practice.

The popularity of the Year In Review breast cancer relies on an unbiased selection of high quality research which is presented in an interactive form and discussed in the Indian context. A wide range of topics is reviewed ranging from Translational science to Supportive care. This aims to give participants clear visibility on how they can apply this information to their immediate practice, as well as keeping in mind the potential of new research.

Another important highlight of this meeting, is that it features experts who have been consistently part of this conference for the last 5 years. These experts understand the participants needs and expectations, while they contextualize and process new information for optimizing patient care.

**This virtual meeting take place over 6 days and will be broadly classified in the following sessions:**

- Monday : Loco-regional therapies in breast cancer
- Tuesday : HR positive Breast Cancer
- Wednesday : HER2 positive Breast Cancer
- Thursday : Triple Negative Breast Cancer
- Friday : Translational science & Supportive care
- Saturday : Keynote presentations and panel discussions

Please find below the registration link for the conference. We request you to popularise this link amongst your colleagues and students.

**www.yearinreview.in/yir2021**

YIR has become an important annual meeting in India for breast cancer. We have been going strong since 2016 with your support and partnership. We urge you to be part of YIR this year as well.

We look forward to your participation in 2021.

With best wishes,

**Organizing Chairperson**


**Dr. Sudeep Gupta**
Director, ACTREC,
Professor of Medical Oncology,
Tata Memorial Centre, Mumbai
sudeepgupta04@yahoo.com

**Dr. Shona Nag**
Director of Oncology,
Sahyadri Hospital,
Pune
shonanag3@gmail.com


Click on the link to register

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The year that was...2020

**11th - 16th JAN 2021**

## Highlights of the Meeting

- Select publications shortlisted from 30+ journals
- Selected abstracts for major cancer conferences
- State of the art keynote talks
- Meet national experts
- Extended rapid review session

## Session Classification

- 11th Jan, Monday : Loco-Regional therapies in breast cancer
- 12th Jan, Tuesday : HR+ve Breast Cancer
- 13th Jan, Wednesday : HER2+ve Breast Cancer
- 14th Jan, Thursday : Triple Negative Breast Cancer
- 15th Jan, Friday : Translational Science & Supportive Care
- 16th Jan, Saturday : Keynote Presentations and Panel Discussions

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# 6th YEAR IN REVIEW BREAST CANCER

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## International Speaker

### Dr. Shaheenah Dawood

Consultant, Dept. of Medical Oncology,
Mediclinic Parkview Hospital,
Dubai

Dr. Shaheenah Dawood is the Head of Medical Oncology and the Head of the Breast Cancer Program at Dubai Hospital in the United Arab Emirates. Dr. Dawood completed her M.B.B.Ch at Dubai Medical College in 1998 and a Master of Public Health degree at the Harvard School of Public Health, Boston, USA in 2008. Her postgraduate medical training programs include a Fellowship at McGill University in Canada in 2006, and the Susan Komen Breast Cancer Fellowship at the University of Texas M.D. Anderson Cancer Center in 2007.

Dr. Dawood is a member of various professional organizations, including the American Society of Clinical Oncology (ASCO), the American Association of Cancer Research (AACR), the Canadian Association of Medical Oncologists, the Emirates Medical Association, and the Inflammatory Breast Cancer Research Group. She is also the co-director of the Middle East Research Network.

Dr. Dawood has been a primary author or collaborator on over 50 peer-reviewed publications in national and international journals. In addition, she has collaborated with other authors to write a number of book chapters. Dr. Dawood has also been involved as a journal reviewer and as an editorial consultant for many cancer-related journals.

Research Interests- Dr. Dawood's researcher interests encompass Triple Negative Breast Cancer, Inflammatory Breast Cancer, Metastases, as well as life-style issues and survival outcome of cancer patients.

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## International Speaker

### Prof. Rebecca Dent

Head & Senior Consultant,
Medical Oncology, National Cancer Centre,
Singapore

Professor Dent's primary research interest is in the field of breast cancer, with a focus on locally advanced breast cancer and triple negative/basal-like breast cancers. She has served as Chair of the locally advanced breast cancer program and Head, Breast Cancer Clinical Trials at the Sunnybrook Odette Cancer Center in Toronto, Ontario Canada from 2008-2011. They were actively developing novel therapies and imaging strategies for these high risk patients and up to 75% of their locally advanced breast cancer patients were enrolled onto one or more trials. Recognized as a national leader in triple negative breast cancers with several publications in this area with over 4,000 citations including three citations in the New England Journal of Medicine, she has been invited to speak about her research at major cancer centers in Canada, US, Asia and Europe.

Since beginning her position in February 2011 as a consultant and now senior consultant at the National Cancer Center in Singapore, she has founded and co-chaired the 5th Asia Pacific Breast Cancer Summit. This is a multidisciplinary meeting for the treatment of breast cancer in which are able to attract almost 400 attendees from over 25 countries in the region and globally. She serves on a number of internal steering committees for clinical trials for breast cancer as well as the principal investigator for trials investigating novel therapies for patients with triple negative breast cancer. Finally she serves on a number of prominent international committees such as the American Society of Clinical Oncology (ASCO) Scientific Committee (ER/HER2 track) and the Editorial Board of the Journal of Clinical Oncology. Most recently, she was the only ex-US participant in the ASCO Leadership Development Program.

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## International Speakers

### Dr. Shanu Modi

Consultant Medical Oncologist,
Memorial Sloan Kettering Cancer Center,
New York, USA

Dr. Modi completed her Medical Oncology Training at The Cross Cancer Institute following her medical degree from the University of Alberta in Edmonton, Canada. She then pursued a special research fellowship in breast oncology at Memorial Sloan Kettering Cancer Center in New York and joined the Breast Medicine Service as an Attending Physician in 2005. She has a practice dedicated solely to the treatment of patients with breast cancer and her research is focused on early phase clinical drug development. At MSKCC she has been leading the translational efforts towards novel therapies for HER2+ Breast Cancer. In 2009 she received the Advanced Clinical Research Award from the American Society of Clinical Oncology and the same year she was awarded the Patricia and James Cayne Chair for Junior Faculty in view of her research contributions. She has authored numerous peer-reviewed papers and has presented her work at many international meetings and is also involved in mentoring Fellows and Junior Faculty.

### Dr. Ashutosh Kothari

Onco-Plastic Breast Surgeon & Clinical Lead,
Guy's & St. Thomas NHS Foundation Trust,
London, UK

Dr. Kothari completed his super-speciality training in surgical oncology at the prestigious Tata Memorial Hospital, Mumbai, India. He moved to London in 1999 and has worked in the Breast Unit at Guys Hospital since. Dr. Ashutosh Kothari is skilled in all techniques of onco-plastic breast surgery as well as implant based breast reconstruction. He has a special interest in hereditary breast cancer and breast cancer in young women.

He is the clinical lead in breast surgery as well as the lead of the breast team. He is on the faculty of a number of international onco-plastic breast surgery and implant based breast reconstruction courses as well as conferences. He is co-director of the London Implant and ADM Masterclass, held each year at Guy's.

Dr. Ashutosh is a co-investigator on the world's first prospective implant and acellular dermal matrix based breast reconstruction clinical trial.

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## International Speaker

### Prof. Sherene Loi

Professor, Cancer Therapeutics
Head, Translational Breast Cancer Genomics and Therapeutics Lab,
Peter MacCallum Cancer Centre
University of Melbourne, Melbourne, Australia

Professor Loi is a medical oncologist specialized in breast cancer as well as a clinician scientist with expertise in genomics, immunology and drug development including immunotherapy. She is working in Peter MacCallum Cancer Centre, in Melbourne, Australia as well as Consultant Medical Oncologist in the Breast Service and head of the Breast Cancer Clinical Trials Unit.

To date, She has published over 220 peer-reviewed research articles with a lifetime H index of 74. She has been a Web of Science Highly Cited Author for 3 years in a row. Professor Loi is a Board Director as well as a member of the Scientific Advisory Committee of the Australia New Zealand Breast Cancer Trials Group (BCT Australia/NZ).

She also Co-Chairs the Scientific Executive Committee and the Translational Working Group of the International Breast Cancer Study Group (IBCSG) based in Bern, Switzerland. She is the current holder of the Inaugural National Breast Cancer Foundation (NBCF) of Australia Endowed Chair and a research fellow of the Breast Cancer Research Foundation (BCRF), New York and is on the Scientific Committee for Breast Cancer for the American Society of Clinical Oncology (ASCO).

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## Day 1 - Monday 11th January, 2021

### Scientific Program

#### Session 1: Locoregional Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

Welcome Address **Dr.Sudeep Gupta & Dr.Shona Nag**

**10 Mins**

**Reviewer: Dr. Shalaka Joshi, Surgical Oncologist, Mumbai**

Breast Conservation After Neoadjuvant Chemotherapy for Triple-Negative Breast Cancer: Surgical Results From the BrighTNess Randomized Clinical Trial

*Author: Mehra Golshan*
*Citation: JAMA Surg.2020 Mar 1;155(3):e195410.*

Impacts of omission of breast cancer surgery in older women with ER+ early breast cancer. A risk stratified analysis of survival and quality of life outcomes

*Author: L. Wyld*
*Citation: European Journal of Cancer 138, Suppl. 1 (2020) S3-S17*

**10 Mins**

**Reviewer: Dr. Vaishali Zamre, Surgical Oncologist, Delhi**

First-in-human robotic supermicrosurgery using a dedicated microsurgical robot for treating breast cancer-related lymphedema: a randomized pilot trial

*Author: Tom J. M. van Mulken*
*Citation: Nat Commun. 2020; 11: 757*

Radioactive Iodine Seed Localisation in the Axilla with the Sentinel Node Procedure: The RISAS Trial

*Author: Janine Simons*
*Citation: SABCS 2020 GS1-10*

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**Reviewer: Dr. Sujana Priya, Radiation Oncologist, Hyderabad**

Hypofractionated breast radiotherapy for 1 week versus 3 weeks (FAST-Forward): 5-year efficacy and late normal tissue effects results from a multicentre, non-inferiority, randomised, phase 3 trial

*Author: Adrian Murray Brunt*
*Citation: Lancet.2020 May 23;395(10237):1613-1626*

Hypofractionated Versus Standard Fractionated Radiotherapy in Patients With Early Breast Cancer or Ductal Carcinoma In Situ in a Randomized Phase III Trial: The DBCG HYPO Trial

*Author: Birgitte V. Offersen*
*Citation: Journal of Clinical Oncology 38, no. 31 (November 01, 2020) 3615-3625*

**10 Mins**

**Reviewer: Dr. Neha Choudhary, Surgical Oncologist, Kolkata**

Effect of mammographic screening from age 40 years on breast cancer mortality (UK Age trial): final results of a randomised, controlled trial

*Author: Duffy SW*
*Citation: Lancet Oncol 2020; August 12, 2020. https://doi.org/10.1016/S1470-2045(20)30398-3*

Incidence, Characteristics, and Outcomes of Interval Breast Cancers Compared With Screening-Detected Breast Cancers

*Author: Saroj Niraula*
*Citation: AMA Netw Open. 2020;3(9):e2018179*

**10 Mins**

**Reviewer: Dr. Mitesh Shetty, Medical Genetics, Banaglore**

Prevalence of Pathogenic Variants in Cancer Susceptibility Genes Among Women With Postmenopausal Breast Cancer

*Author: Allison W. Kurian*
*Citation: JAMA. 2020 Mar 10; 323(10): 995-997*

Pregnancy After Breast Cancer in Patients With Germline BRCA Mutations

*Author: Matteo Lambertini*
*Citation: Clin Oncol.2020 Sep 10;38(26):3012-3023*

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**10 Mins**

**Reviewer: Dr. Aparna Dhar, Medical Genetics, Delhi**

Management of Hereditary Breast Cancer: American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Guideline

*Author: Nadine M. Tung*
*Citation: Journal of Clinical Oncology 38, no. 18 (June 20, 2020) 2080-2106*

Characterization of the Cancer Spectrum in Men With Germline BRCA1 and BRCA2 Pathogenic Variants: Results From the Consortium of Investigators of Modifiers of BRCA1/2 (CIMBA)

*Author: Valentina Silvestri*
*Citation: JAMA Oncol.2020 Aug 1;6(8):1218-1230.doi: 10.1001/jamaoncol.2020.2134*

**10 Mins**

**Reviewer: Dr. Anusheel Munshi, Radiation Oncologist, Delhi**

PRIME 2 randomized trial (Postoperative Radiotherapy in Minimum-Risk Elderly): wide local excision and adjuvant hormonal therapy +/- whole breast irradiation in women ≥65 years with early invasive breast cancer: 10 year results

*Author: Kunkler IH*
*Citation: SABCS 2020 GS2-03*

Long term survival and local control outcomes from single dose targeted intraoperative radiotherapy during lumpectomy (TARGIT-IORT) for early breast cancer: TARGIT-A randomised clinical trial

*Author: Jayant S Vaidya*
*Citation: BMJ.2020 Aug 19;370:m2836*

**10 Mins**

**Reviewer: Dr. Garvit Chitkara, Surgical Oncologist, Mumbai**

A randomized phase III trial of systemic therapy plus early local therapy versus systemic therapy alone in women with de novo stage IV breast cancer: A trial of the ECOG-ACRIN Research Group (E2108)

*Author: Seema Ahsan Khan*
*Citation: ASCO 2020 LBA 2*

Long-term Oncologic Outcomes of Immediate Breast Reconstruction vs Conventional Mastectomy Alone for Breast Cancer in the Setting of Neoadjuvant Chemotherapy

*Author: Zhen-Yu Wu*
*Citation: JAMA Surg. 2020;155(12):1142-1150*

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Day 1

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**15 Mins**

**Rapid Review I**

**Reviewer: Dr. Nita Nair, Surgical Oncologist, Mumbai**

- Association Between 21-Gene Assay Recurrence Score and Locoregional Recurrence Rates in Patients With Node-Positive Breast Cancer

  *Author: Wendy A. Woodward*
  *Citation: JAMA Oncol. 2020;6(4):505-511*

- Imaging Phenotypes of Breast Cancer Heterogeneity in Preoperative Breast Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) Scans Predict 10-Year Recurrence

  *Author: Rhea D Chitalia*
  *Citation: Clin Cancer Res. 2020 Feb 15;26(4):862-869*

- Clinical Utility of a Hand-Held Scanner for Breast Cancer Early Detection and Patient Triage

  *Author: Julie M Clanahan*
  *Citation: JCO Glob Oncol. 2020 Feb;6:27-34*

- Association of Germline Genetic Testing Results With Locoregional and Systemic Therapy in Patients With Breast Cancer

  *Author: Allison W. Kurian*
  *Citation: JAMA Oncol. 2020;6(4):e196400*

- Cancer Risks Associated With Germline PALB2 Pathogenic Variants: An International Study of 524 Families

  *Author: Xin Yang*
  *Citation: J Clin Oncol. 2020 Mar 1;38(7):674-685*

- Prognostic Impact of the 21-Gene Recurrence Score Assay Among Young Women With Node-Negative and Node-Positive ER-Positive/HER2-Negative Breast Cancer

  *Author: Philip D Poorvu*
  *Citation: J Clin Oncol. 2020 Mar 1;38(7):725-733*

- Trends in Parity and Breast Cancer Incidence in US Women Younger Than 40 Years From 1935 to 2015

  *Author: Sarah M. Lima*
  *Citation: JAMA Netw Open. 2020 Mar; 3(3): e200929*

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- International evaluation of an AI system for breast cancer screening

  *Author: Scott Mayer McKinney*
  *Citation: Nature,volume 577, pages89-94(2020)*

- Cost-effectiveness of Breast Cancer Screening With Magnetic Resonance Imaging for Women at Familial Risk

  *Author: H Amarens Geuzinge*
  *Citation: JAMA Oncol. 2020 Sep 1;6(9):1381-1389*

- Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women

  *Author: Siva Teja Kakileti*
  *Citation: JCO Glob Oncol. 2020 Oct;6:1472-1480*

**15 Mins**

**Rapid Review II**

**Reviewer: Dr. Geeta Kadayaprath, Surgical Oncologist, Delhi**

- Nodal positivity decreases with age in women with early-stage, hormone receptor-positive breast cancer

  *Author: Stephanie M Downs-Canner*
  *Citation: Cancer.2020 Mar 15;126(6):1193-1201*

- Cluster randomised trial to evaluate the clinical benefits of decision support interventions for older women with operable breast cancer

  *Author: L. Wyld*
  *Citation: European Journal of Cancer 138, Suppl. 1 (2020) S3-S17*

- The risk of late breast cancer recurrence in Denmark during 17 years of follow-up

  *Author: R.N. Pedersen*
  *Citation: Annals of Oncology (2020) 31 (suppl_2): S83-S87.10.1016/annonc annonc123*

- Meta-Analysis of Prevalence of Triple-Negative Breast Cancer and Its Clinical Features at Incidence in Indian Patients With Breast Cancer

  *Author: Apurv Kulkarni*
  *Citation: JCO Global Oncology no. 6 (2020) 1052-1062. Published online July 8, 2020*

- Association Between Time to Operation and Pathologic Stage in Ductal Carcinoma in Situ and Early-Stage Hormone Receptor-Positive Breast Cancer

  *Author: Christina A Minami*
  *Citation: Journal of americal college of surgeons.,ORIGINAL SCIENTIFIC ARTICLE| VOLUME 231, ISSUE 4, P434-447.E2, OCTOBER 01, 2020*

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# 6th YEAR IN REVIEW BREAST CANCER

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## Day 1 - Monday 11th January, 2021

### Scientific Program

#### Session 1: Locoregional Breast Cancer

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- Quantifying the Impact of Axillary Surgery and Nodal Irradiation on Breast Cancer-Related Lymphedema and Local Tumor Control: Long-Term Results From a Prospective Screening Trial

  *Author: Alphonse G Taghian*
  *Citation: J Clin Oncol. 2020 Oct 10;38(29):3430-3438*

- Persistent controlled substance use following mastectomy with reconstruction surgery

  *Author*: Jacob C Cogan
  *Citation: SABCS 2020 GS3-08*

- Development and validation of a magnetic resonance imaging radiomics-based signature to predict axillary lymph node metastasis and disease-free survival in patients with breast cancer: A multicenter cohort study

  *Author*: Herui Yao
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S303-S339. 10.1016/annonc/annonc267*

**15 Mins**

**Rapid Review III**

**Reviewer: Dr. Sanjay M H, Radiation Oncologist, Pune**

- A randomized phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in situ (DCIS) of the breast (BIG 3- 07/TROG 07.01

  *Author*: Boon Hui Chua
  *Citation: SABCS2020 GS2-04*

- Primary results of NRG Oncology / NSABP B-43: Phase III trial comparing concurrent trastuzumab (T) and radiation therapy (RT) with RT alone for women with HER2-positive ductal carcinoma in situ (DCIS) after lumpectomy.

  *Author*: Melody A. Cobleigh
  *Citation: ASCO 2020 Abstract 508*

- Identifying patients whose symptoms are under-recognized during breast radiotherapy: Comparison of patient and physician reports of toxicity in a multicenter cohort

  *Author*: Jagsi R
  *Citation: SABCS 2020 GS3-07*

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## Day 1 - Monday 11th January, 2021

### Scientific Program

#### Session 1: Locoregional Breast Cancer

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- Toward Improving Patients Experiences of Acute Toxicity From Breast Radiotherapy: Insights From the Analysis of Patient-Reported Outcomes in a Large Multicenter Cohort

  *Author*: *Reshma Jagsi*
  *Citation: Journal of Clinical Oncology 38, no. 34 (December 01, 2020) 4019-4029*

- Accelerated Partial-Breast Irradiation Compared With Whole-Breast Irradiation for Early Breast Cancer: Long-Term Results of the Randomized *Phase III APBI-IMRT-Florence Trial*

  *Author*: *Icro Meattini*
  *Citation: J Clin Oncol.2020 Dec 10;38(35):4175-4183*

- Long-term primary results of accelerated partial breast irradiation after breast-conserving surgery for early-stage breast cancer: a randomised, phase 3, equivalence trial

  *Author*: Frank A Vicini
  *Citation: Lancet.2019 Dec 14;394(10215):2155-2164*

- Hypofractionated Versus Conventional Fractionated Radiotherapy After Breast-Conserving Surgery in the Modern Treatment Era: A Multicenter, Randomized Controlled Trial From China

  *Author*: Shu-Lian Wang
  *Citation: Journal of Clinical Oncology 38, no. 31 (November 01, 2020) 3604-3614*

- Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of Oligometastatic Cancers: Long-Term Results of the SABR-COMET Phase II Randomized Trial

  *Author*: David A. Palma
  *Citation: Journal of Clinical Oncology 38, no. 25 (September 01, 2020) 2830-2838*

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Day 1

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

- Highlights of Day 1 Loco-regional Breast Cancer session
- Speaker: Dr. Vani Parmar, Surgical Oncologist, Mumbai

**5 Mins**

Introduction by **Dr. Sudeep Gupta**

**10 Mins**

- Reviewer: Dr. Bhuvan Chugh, Medical Oncologist, Delhi
- Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer (monarchE)

  *Author: Stephen R D Johnston*
  *Citation: J Clin Oncol. 2020 Dec 1;38(34):3987-3998*

- Primary outcome analysis of invasive disease-free survival for monarchE: abemaciclib combined with adjuvant endocrine therapy for high risk early breast cancer

  *Author: O'Shaughnessy JA*
  *Citation: SABCS Abstract GS1-01*

**10 Mins**

- Reviewer: Dr. Mansi Khanderia, Medical Oncologist, Bangalore
- PALLAS: A randomized phase III trial of adjuvant palbociclib with endocrine therapy versus endocrine therapy alone for HR+/HER2- early breast cancer

  *Author: Erica Mayer*
  *Citation:* Annals of Oncology (2020) 31 (suppl_4): S1142-S121510
  *101/annonc/annonc325*

- Phase III study of palbociclib combined with endocrine therapy (ET) in patients with hormone-receptor-positive (HR+), HER2-negative primary breast cancer and with high relapse risk after neoadjuvant chemotherapy (NACT): First results from PENELOPE-B

  *Author: Loibl S*
  *Citation: SABCS 2020 GS1-02*

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Day 2

# 6th YEAR IN REVIEW BREAST CANCER

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

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**15 Mins**

**Reviewer: Dr. Priya Tiwari, Medical Oncologist, Delhi**

Clinical utility of Mamma Print testing in Invasive Lobular Carcinoma: Results from the MINDACT phase III trial

*Author: O. Metzger*
*Citation: Ejc,EBCC 12, Volume 138, Supplement 1,S5-S6,OCTOBER 01, 2020*

First results from a phase III randomized clinical trial of standard adjuvant endocrine therapy (ET) +/- chemotherapy (CT) in patients (pts) with 1-3 positive nodes, hor mone receptor-positive (HR+) and HER2-negative (HER2-) breast cancer (BC) with recurrence score (RS) < 25: SWOG S1007 (RxPonder)

*Author: Kevin Kalinsky*
*Citation: SABCS 2020 GS3-00*

Long-term outcome and prognostic value of Ki67 after perioperative endocrine therapy in postmenopausal women with hormone-sensitive early breast cancer (POETIC): an open-label, multicentre, parallel-group, randomised, phase 3 trial

*Author: Ian Smith*
*Citation: The Lancet.,VOLUME 21, ISSUE 11, P1443-1454, NOVEMBER 01, 2020*

**10 Mins**

**Reviewer: Dr. Joydeep Ghosh, Medical Oncologist, Kolkata**

nextMONARCH: Final overall survival analysis of abemaciclib monotherapy or in combination with tamoxifen in patients with HR+, HER2- metastatic breast cancer

*Author: Hamilton EP*
*Citation: ESMO Virtual Congress 2020 : abstract 2730*

PALOMA-3 Exploratory Analysis: Who Benefits Most From Palbociclib? (Predictors of efficacy in patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative advanced breast cancer: Subgroup analyses of PALOMA-3)

*Author: Rugo H*
*Citation: European Breast Conference 2020, Abstract 9*

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**15 Mins**

**Reviewer: Dr. M Vamshi Krishna, Medical Oncologist, Hyderabad**

Overall Survival with Ribociclib plus Fulvestrant in Advanced Breast Cancer

*Author: Dennis J. Slamon*
*Citation: N Engl J Med 2020; 382:514-524*

Abemaciclib plus trastuzumab with or without fulvestrant versus trastuzumab plus standard-of-care chemotherapy in women with hormone receptor-positive, HER2-positive advanced breast cancer (monarcHER): a randomised, open-label, phase 2 trial

*Author: Sara M. Tolaney*
*Citation: The Lancet VOLUME 21, ISSUE 6, P763-775, JUNE 01, 2020*

Estrogen and Progesterone Receptor Testing in Breast Cancer: ASCO/CAP Guideline Update

*Author: Kimberly H Allison*
*Citation: J Clin Oncol.2020 Apr 20;38(12):1346-1366*

**10 Mins**

**Reviewer: Dr. Mansi Shah, Medical Oncologist, Ahemdabad**

PARSIFAL: A randomized, multicenter, open-label, phase II trial to evaluate palbociclib in combination with fulvestrant or letrozole in endocrine-sensitive patients with estrogen receptor (ER)[+]/HER2[-] metastatic breast cancer

*Author: Antonio Llombart-Cussac*
*Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1007-1007*

LBA19 - GEICAM/2014-12 (FLIPPER) study: First analysis from a randomized phase II trial of fulvestrant (F)/palbociclib (P) versus (vs) F/placebo (PL) as first-line therapy in postmenopausal women with HR (hormone receptor)+/HER2- endocrine sensitive advanced breast cancer (ABC

*Author: Joan Albanell*
*Citation: Annals of Oncology (2020) 31 (suppl_4): S1142-S1215. 10.1016/annonc/annonc325*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

**Reviewer: Dr. Deepak Koppaka, Medical Oncologist, Hyderabad**

LBA18 - Overall survival (os) results from SOLAR-1, a phase III study of alpelisib (ALP) + fulvestrant (FUL) for hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (ABC)

*Author: Fabrice André*
*Citation: Annals of Oncology (2020) 31 (suppl_4): S1142-S1215. 10.1016/annonc/annonc325*

Interim results of a phase I/Ib study of LSZ102, an oral selective estrogen receptor degrader, in combination with ribociclib or alpelisib in patients with ER+ breast cancer who had progressed after endocrine therapy.2020 ESMO Breast Cancer Virtual Meeting. Abstract

*Author: Jhaveri Komal*
*Citation: LBA1. Presented May 24, 2020*

**10 Mins**

**Reviewer: Dr. Chintan Shah, Medical Oncologist, Ahemdabad**

Alpelisib (ALP) + fulvestrant (FUL) in patients (pts) with PIK3CA-mutated (mut) hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (ABC) previously treated with cyclin-dependent kinase 4/6 inhibitor (CDKi) + aromatase inhibitor (AI): BYLieve study results

*Author: Hope S. Rugo*
*Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1006-1006*

Response of Brain Metastases From PIK3CA-Mutant Breast Cancer to Alpelisib

*Author: Felipe Batalini*
*Citation: JCO Precision Oncology no. 4 (2020) 572-578*

**10 Mins**

**Reviewer: Dr. Adwaita Gore, Medical Oncologist, Mumbai**

Pooled analysis of patient (pt)-reported quality of life (QOL) in the MONALEESA (ML)-2, -3, and -7 trials of ribociclib (RIB) plus endocrine therapy (ET) to treat hormone receptor–positive, HER2-negative (HR+/HER2−) advanced breast cancer (ABC)

*Author: Peter A. Fasching*
*Citation: Annals of Oncology (2020) 31 (suppl_4): S348-S395*

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Day 2

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Updated overall survival (OS) results from the phase III MONALEESA-7 trial of pre- or perimenopausal patients with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2−) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib

  *Author: Debu Tripathy*
  *Citation: SABCS 2020 PD2-04*

**15 Mins**

**Rapid Review I**

**Reviewer: Dr. Jaya Ghosh, Medical Oncologist, Mumbai**

- 12 year results of anastrozole versus tamoxifen for the prevention of breast cancer in postmenopausal women with locally excised ductal carcinoma in- situ

  *Author: Ivana Sestak*
  *Citation: SABCS 2020 GS2-02*

- Association of Chemotherapy With Survival in Elderly Patients With Multiple Comorbidities and Estrogen Receptor-Positive, Node-Positive Breast Cancer

  *Author: Nina Tamirisa*
  *Citation: JAMA Oncol. 2020 Oct 1;6(10):1548-1554*

- Management of Male Breast Cancer: ASCO Guideline

  *Author: Michael J Hassett*
  *Citation: J Clin Oncol.2020 Jun 1;38(16):1849-1863*

- Adding Ovarian Suppression to Tamoxifen for Premenopausal Breast Cancer: A Randomized Phase III Trial

  *Author: Hyun-Ah Kim*
  *Citation: J Clin Oncol. 2020 Feb 10;38(5):434-443*

- Denosumab (Dmab) as add-on to different regimen of nab-paclitaxel (nP)-anthracycline based neoadjuvant chemotherapy (NACT) in early breast cancer (BC): Subgroup analyses by RANK expression and HR status

  *Author: Theresa Link*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S303-S339. 10.1016/annonc/annonc267*

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# 6th YEAR IN REVIEW BREAST CANCER

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Neoadjuvant chemotherapy and immunotherapy in Luminal B BC: Results of the phase II GIADA trial

  *Author: Maria Vittoria Dieci*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S303-S339. 10.1016/annonc/annonc267*

- Letrozole + ribociclib versus letrozole + placebo as neoadjuvant therapy for ER+ breast cancer (FELINE trial)

  *Author: Qamar J. Khan*
  *Citation: J Clin Oncol 38: 2020 (suppl; abstr 505)*

- Potent Cell-Cycle Inhibition and Upregulation of Immune Response with Abemaciclib and Anastrozole in neoMONARCH, Phase II Neoadjuvant Study in HR +/HER2 - Breast Cancer

  *Author: Sara A Hurvitz*
  *Citation: Clin Cancer Res. 2020 Feb 1;26(3):566-580*

- Neoadjuvant nab-paclitaxel weekly versus dose-dense paclitaxel followed by dose-dense EC in high risk HR+/HER2- early BC by: results from the neoadjuvant part of ADAPT HR+/HER2- trial

  *Author: S Kuemmel*
  *Citation: SABCS 2020 GS4-003*

- Endocrine therapy alone in patients with intermediate or high-risk luminal early breast cancer (0-3 lymph nodes), Recurrence Score <26 and Ki67 response after preoperative endocrine therapy: Primary outcome results from the WSG-ADAPT HR+/HER2- trial

  *Author: N Harbeck*
  *Citation: SABCS 2020 GS4-04*

- Neoadjuvant chemotherapy (NCT) response in postmenopausal women with clinical stage II or III estrogen receptor positive (ER+) and HER2 negative (HER2-) breast cancer (BC) resistant to endocrine therapy (ET) in the ALTERNATE trial (Alliance A011106)

  *Author: Cynthia X Ma*
  *Citation: SABCS GS4-05*

**15 Mins**

**Rapid Review II**

**Reviewer: Dr. Rahul Kulkarni, Medical Oncologist, Mumbai**

- Association of Endocrine Therapy With Overall Survival in Women With Small, Hormone Receptor–Positive, ERBB2-Negative Breast Cancer

  *Author: Sung Jun Ma*
  *Citation: JAMA Netw Open.2020;3(8):e2013973*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Ipatasertib (IPAT) + paclitaxel (PAC) for PIK3CA/AKT1/PTEN-altered hormone receptor-positive (HR+) HER2-negative advanced breast cancer (aBC): Primary results from Cohort B of the IPATunity130 randomised phase III trial

  *Author: Nicholas Turner*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S348-S395*

- Fulvestrant plus capivasertib versus placebo after relapse or progression on an aromatase inhibitor in metastatic, oestrogen receptor-positive breast cancer (FAKTION): A multicentre, randomised, controlled, phase 2 trial

  *Author: Robert H Jones*
  *Citation: Lancet Oncol. 2020 Mar;21(3):345-357*

- Effect of Eribulin With or Without Pembrolizumab on Progression-Free Survival for Patients With Hormone Receptor-Positive, ERBB2-Negative Metastatic Breast Cancer: A Randomized Clinical Trial

  *Author: Sara M Tolaney*
  *Citation: JAMA Oncol 2020 Oct 1;6(10):1598-1605*

- E2112: Randomized phase III trial of endocrine therapy plus entinostat/placebo in patients with hormone receptor-positive advanced breast cancer: A trial of the ECOG-ACRIN Cancer Research Group"

  *Author: Roisin M Connolly*
  *Citation: SABCS 2020 GS4-02*

- CONTESSA: A phase 3 study of tesetaxel plus a reduced dose of capecitabine versus capecitabine alone in patients with HER2-, hormone receptor + (HR+) metastatic breast cancer (MBC) who have previously received a taxane

  *Author: O'Shaughnessy J*
  *Citation: SABCS 2020 GS4-01*

- Clinical efficacy and molecular effects of lenvatinib (Len) and letrozole (Let) in hormone receptor-positive (HR+) metastatic breast cancer (MBC)

  *Author: Joline Si Jing Lim*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1019-1019*

- PADA-1: A randomized, open label, multicentric phase III trial to evaluate the safety and efficacy of palbociclib in combination with hormone therapy driven by circulating DNA ESR1 mutation monitoring in ER-positive, HER2-negative metastatic breast cancer patients

  *Author: Francois Clement Bidard*
  *Citation: Journal of Clinical Oncology 36, no. 15_suppl,Published online June 01, 2018*

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Day 2

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- ESR1 Mutations and Overall Survival on Fulvestrant versus Exemestane in Advanced Hormone Receptor-Positive Breast Cancer: A Combined Analysis of the Phase III SoFEA and EFECT Trials

  *Author: Nicholas C. Turner*
  *Citation: Clin Cancer Res October 1 2020 (26) (19) 5172-5177;*

- Breast Cancer Index (BCI) predicts benefit of two-and-a-half versus five years of extended endocrine therapy in HR+ breast cancer patients treated in the IDEAL trial

  *Author: Gerrit-Jan Liefers*
  *Citation: J Clin Oncol 38: 2020 (suppl; abstr 512)*

**15 Mins**

**Rapid Review III**

**Reviewer: Dr. Nitesh Rohatgi, Medical Oncologist, Delhi**

- Clinicopathological Characteristics and Breast Cancer-Specific Survival of Patients With Single Hormone Receptor-Positive Breast Cancer

  *Author: Yunhai Li*
  *Citation: JAMA Netw Open. 2020 Jan 3;3(1):e1918160.*
  *doi: 10.1001/jamanetworkopen.2019.18160*

- Outcome and molecular landscape of patients with PIK3CA-mutated metastatic breast cancer

  *Author: Mosele F*
  *Citation: Ann Oncol. 2020 Mar;31(3):377-386*

- Double PIK3CA mutations in cis increase oncogenicity and sensitivity to PI3Kα inhibitors

  *Author: Neil Vasan*
  *Citation: AM2020-NG16 Published August 2020. DOI: 10.1158/1538-7445*

- Clinicopathological characteristics and prognosis of breast cancer patients with isolated central nervous system metastases in the multicentre ESME database

  *Author: Marcela Carausu*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S348-S395.*
  *10.1016/annonc/annonc268*

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# 6th YEAR IN REVIEW BREAST CANCER

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## Day 2 - Tuesday 12th January, 2021

### Scientific Program

**Session 2: Hormone Receptor Positive Breast Cancer**

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Clinical outcomes of alpelisib plus fulvestrant in hormone receptor-positive, human epidermal growth factor receptor-2-negative advanced breast cancer with PIK3CA alterations detected in plasma ctDNA by next-generation sequencing: Biomarker analysis from the SOLAR-1 study

  *Author: Ciruelos EM*
  *Citation: SABCS 2020 PD2-06*

- Response to neoadjuvant chemotherapy and the 21-gene breast recurrence score in young women with estrogen receptor-positive early breast cancer

  *Author: Tal Sella*
  *Citation: J Clin Oncol 38: 2020 (suppl; abstr 514)*

- Development and validation of a tool integrating the 21-gene recurrence score and clinicopathlogic features to individualize prognosis for distant recurrence and prediction of absolute chemotherapy benefit in early breast cancer

  *Author: Joseph A Fatima*
  *Citation: SABCS 2020 GS4-10*

- MINDACT: Long-term results of the large prospective trial testing the 70-gene signature MammaPrint as guidance for adjuvant chemotherapy in breast cancer patients

  *Author: Fatima Cardoso*
  *Citation: J Clin Oncol 38: 2020 (suppl; abstr 506)*

- How low is low risk: MINDACT updated outcome and treatment benefit in patients considered clinical low risk and stratified by genomic signature, age and nodal status

  *Author: Laura J van't Veer1*
  *Citation: SABCS GS4-11*

- Validation of MAF biomarker for response prediction to adjuvant bisphosphonates in 2 clinical trials: AZURE and NSABP-B34

  *Author: Alexander H. G. Paterson*
  *Citation: J Clin Oncol 38: 2020 (suppl; abstr 513*

- Identifying oncogenic drivers associated with increased risk of late distant recurrence in postmenopausal, estrogen receptor-positive, HER2-negative early breast cancer: results from the BIG 1-98 study

  *Author: S J Luen*
  *Citation: Annals of Oncology VOLUME 31, ISSUE 10, P1359-1365, OCTOBER 01, 2020*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 3, Wednesday 13th January 2021

## Scientific Program

### Session 3: HER2 Positive Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

- Highlights of HR+ Breast Cancer session
- **Speaker: Dr. Govind Babu, Medical Oncologist, Bangalore**

**5 Mins**

Introduction by **Dr. Shona Nag**

**15 Mins**

- **Reviewer: Dr. Rakesh Reddy, Medical Oncologist, Hyderabad**
- Adjuvant trastuzumab emtansine (T-DM1) vs trastuzumab (T) in patients (pts) with residual invasive disease after neoadjuvant therapy for HER2+ breast cancer: Sub group analysis from KATHERINE

  *Author: S. Loibl*
  *Citation: Annals of Oncology (2020) 31 (suppl_2): S48-S53*

- Biomarker data from KATHERINE: A phase III study of adjuvant trastuzumab emtansine (T-DM1) versus trastuzumab (H) in patients with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer

  *Author: Carsten Denkert*
  *Citation: ASCO 2020 Abstract 502*

- De-escalated chemotherapy versus endocrine therapy plus pertuzumab+ trastuzumab for HR+/HER2+ early breast cancer (BC): First efficacy results from the neoadjuvant WSG-TP-II study

  *Author: Oleg Gluz*
  *Citation: J Clin Oncol 38: 2020 (suppl; ASCO abstr 515)*

**10 Mins**

- **Reviewer: Dr. Seema Gulia, Medical Oncologist, Mumbai**
- Three-year follow-up of neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2-blockade for HER2-positive breast cancer (TRAIN-2): A randomized phase III trial

  *Author: Anna van der Voort*
  *Citation:ASCO Abstract 501*

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# 6th YEAR IN REVIEW BREAST CANCER

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## Day 3, Wednesday 13th January 2021

## Scientific Program

### Session 3: HER2 Positive Breast Cancer

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Chemotherapy (CT) de-escalation using an FDG-PET/CT (F-PET) and pathological response-adapted strategy in HER2[+] early breast cancer (EBC): PHERGain Trial.

*Author: Javier Cortes*
*Citation: ASCO Abstract 503*

**15 Mins**

**Reviewer: Dr. Chakor Vora, Medical Oncologist, Pune**

Evaluation of 1-Year vs Shorter Durations of Adjuvant Trastuzumab Among Patients With Early Breast Cancer An Individual Participant Data and Trial-Level Meta-analysis

*Author: Seema Gulia*
*Citation: JAMA Netw Open. 2020;3(8):e2011777*

*Author: Masataka Sawaki*
*Citation: Journal of Clinical Oncology 38, no. 32 (November 10, 2020) 3743-3752*

Abemaciclib plus trastuzumab with or without fulvestrant versus trastuzumab plus standard-of-care chemotherapy in women with hormone receptor-positive, HER2-positive advanced breast cancer (monarcHER): a randomised, open-label, phase 2 trial

*Author: Sara M. Tolaney*
*Citation: The Lancet VOLUME 21, ISSUE 6, P763-775, JUNE 01, 2020*

**15 Mins**

**Reviewer: Dr. Nagender Sharma, Medical Oncologist, Delhi**

Intracranial Efficacy and Survival With Tucatinib Plus Trastuzumab and Capecitabine for Previously Treated HER2-Positive Breast Cancer With Brain Metastases in the HER2CLIMB Trial

*Author: Nancy U Lin*
*Citation: J Clin Oncol. 2020 Aug 10;38(23):2610-2619*

Tucatinib vs placebo added to trastuzumab and capecitabine in previously treated HER2+ metastatic breast cancer with and without brain metastases (HER2CLIMB)

*Author: Giuseppe Curigliano*
*Citation: Annals of Oncology (2020) 31 (suppl_2): S62-S82*

Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer

*Author: Rashmi K. Murthy*
*Citation: N Engl J Med 2020; 382:597-609*

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Day 3

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## Scientific Program

### Session 3: HER2 Positive Breast Cancer

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**15 Mins**

**Reviewer: Dr. Aditya Murali, Medical Oncologist, Bangalore**

Trastuzumab Deruxtecan in Previously Treated HER2-Positive Breast Cancer

*Author: Shanu Modi*
*Citation: N Engl J Med 2020; 382:610-621*

Antitumor Activity and Safety of Trastuzumab Deruxtecan in Patients With HER2-Low-Expressing Advanced Breast Cancer: Results From a Phase Ib Study

*Author: Shanu Modi*
*Citation: J Clin Oncol. 2020 Jun 10;38(17):1887-1896*

CNS metastases in HER2-positive metastatic breast cancer treated with trastuzumab deruxtecan: DESTINY-Breast01 subgroup analyses

*Author: Guy Jerusalem*
*Citation: Annals of Oncology (2020) 31 (suppl_2): S62-S82. 10.1016/annonc/annonc122x*

**10 Mins**

**Reviewer: Dr. Rakesh Pinninti, Medical Oncologist, Hyderabad**

Pertuzumab, trastuzumab, and docetaxel for HER2-positive metastatic breast cancer (CLEOPATRA): end-of-study results from a double-blind, randomised, placebo-controlled, phase 3 study

*Author: Sandra M Swain*
*Citation: Lancet Oncol. 2020 Apr;21(4):519-530.*

Survival, Pathologic Response, and Genomics in CALGB 40601 (Alliance), a Neoadjuvant Phase III Trial of Paclitaxel-Trastuzumab With or Without Lapatinib in HER2-Positive Breast Cancer

*Author: Aranzazu Fernandez-Martinez*
*Citation: Journal of Clinical Oncology 38, no. 35 (December 10, 2020) 4184-4193*

**15 Mins**

**Rapid Review I**

**Reviewer: Dr. Rohit Pai, Medical Oncologist, Mumbai**

HER2-Enriched Subtype and ERBB2 Expression in HER2-Positive Breast Cancer Treated with Dual HER2 Blockade

*Author: Aleix Prat*
*Citation: J Natl Cancer Inst. 2020 Jan 1;112(1):46-54*

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Day 3

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

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## Day 3, Wednesday 13th January 2021

## Scientific Program

### Session 3: HER2 Positive Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Early Trastuzumab Interruption and Recurrence-Free Survival in ERBB2 -Positive Breast Cancer

  *Author: Robert S. Copeland-Halperin*
  *Citation: JAMA Oncol. 2020; 6(12):1971-1972*

- Efficacy and Safety of Trastuzumab Emtansine Plus Capecitabine vs Trastuzumab Emtansine Alone in Patients With Previously Treated ERBB2 (HER2)-Positive Metastatic Breast Cancer

  *Author: Javier Cortés*
  *Citation: A Phase 1 and Randomized Phase 2 Trial JAMA Oncol. 2020 Aug; 6(8): 1-7*

- Association of Survival With Chemoendocrine Therapy in Women With Small, Hormone Receptor-Positive, ERBB2-Positive, Node-Negative Breast Cancer

  *Author: Sung Jun Ma*
  *Citation: JAMA Netw Open. 2020 Apr 1;3(4):e202507*

- PREDIX HER2 trial: Event-free survival and pathologic complete response in clinical subgroups and stromal TILs levels

  *Author: Thomas Hatschek*
  *Citation: Annals of Oncology (2020) 31 (suppl_2): S48-S53*

- A multivariable prognostic score to guide systemic therapy in early-stage HER2-positive breast cancer: a retrospective study with an external evaluation

  *Author: Aleix Prat*
  *Citation: Lancet Oncology, VOLUME 21, ISSUE 11, P1455-1464, NOVEMBER 01, 202*

- FDA Approves New VENTANA HER2 Dual ISH DNA Probe Cocktail Assay for Detection of HER2

  *Author: Hannah Slater*

**15 Mins**

**Rapid Review II**

**Reviewer: Dr. Sainath Bhethanabhotla, Medical Oncologist, Hyderabad**

- Final Efficacy Results of Neratinib in HER2-positive Hormone Receptor-positive Early-stage Breast Cancer From the Phase III ExteNET Trial

  *Author: Arlene Chan*
  *Citation: Clinical Breast cancer October 05, 2020*

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# 6th YEAR IN REVIEW BREAST CANCER

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## Day 3, Wednesday 13th January 2021

## Scientific Program

### Session 3: HER2 Positive Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

- Primary analysis of KAITLIN: A phase III study of trastuzumab emtansine (T-DM1) + pertuzumab versus trastuzumab + pertuzumab + taxane, after anthracyclines as adjuvant therapy for high-risk HER2-positive early breast cancer (EBC).

  *Author: Nadia Harbeck*
  *Citation: ASCO Abstract 500*

- Optimizing Anti-HER2 Therapy in early breast cancer: updates from the KRISTINE trial

  *Author: Maeve A. Hennessy*
  *Citation: Ann Palliat Med. 2020 Mar;9(2):504-509*

- MK-2206 and Standard Neoadjuvant Chemotherapy Improves Response in Patients With Human Epidermal Growth Factor Receptor 2-Positive and/or Hormone Receptor-Negative Breast Cancers in the I-SPY 2 Trial

  *Author: A Jo Chien*
  *Citation: J Clin Oncol. 2020 Apr 1;38(10):1059-1069*

- Safety of trastuzumab emtansine (T-DM1) in patients with HER2-positive advanced breast cancer: Primary results from the KAMILLA study cohort 1

  *Author: Filippo Montemurro*
  *Citation: Eur J Cancer. 2019 Mar;109:92-102*

- Trastuzumab emtansine plus atezolizumab versus trastuzumab emtansine plus placebo in previously treated, HER2-positive advanced breast cancer (KATE2): A phase 2, multicentre, randomised, double-blind trial

  *Author: Leisha A. Emens*
  *Citation: The Lancet VOLUME 21, ISSUE 10, P1283-1295, OCTOBER 01, 2020*

- Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in HER2-Positive Metastatic Breast Cancer Previously Treated With ≥ 2 HER2-Directed Regimens Phase III NALA Trial

  *Author: Cristina Saura*
  *Citation: Journal of Clinical Oncology 38, no. 27 (September 20, 2020) 3138-3149*

- Phase III, Randomized Study of Dual Human Epidermal Growth Factor Receptor 2 (HER2) Blockade With Lapatinib Plus Trastuzumab in Combination With an Aromatase Inhibitor in Postmenopausal Women With HER2-Positive, Hormone Receptor–Positive Metastatic Breast Cancer: Updated Results of ALTERNATIVE

  *Author: Stephen R. D. Johnston*
  *Citation: J Clin Oncol.2020 Aug 21;JCO2001894*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 4, Thursday 14th January 2021

## Scientific Program

### Session 4: Triple Negative Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

- Highlights of HER2+ve Breast Cancer
- **Speaker: Dr. Jyoti Bajpai, Medical Oncologist, Mumbai**

**5 Mins**

Introduction by **Dr. Shona Nag**

**15 Mins**

- **Reviewer: Dr. Babita Kataria, Medical Oncologist, Delhi**
- Adjuvant Capecitabine With Docetaxel and Cyclophosphamide Plus Epirubicin for Triple-Negative Breast Cancer (CBCSG010): An Open-Label, Randomized, Multicenter, Phase III Trial

  *Author: Junjie Li*
  *Citation: Journal of Clinical Oncology 38, no. 16 (June 01, 2020) 1774-1784*

- Effect of Capecitabine Maintenance Therapy Using Lower Dosage and Higher Frequency vs Observation on Disease-Free Survival Among Patients With Early-Stage Triple-Negative Breast Cancer Who Had Received Standard Treatment The SYSUCC-001 Randomized Clinical Trial

  *Author: XI Wang*
  *Citation: JAMA. Published online December 10, 2020. doi:10.1001/jama.2020.23370*

- Phase III trial of metronomic capecitabine maintenance after standard treatment in operable triple-negative breast cancer (SYSUCC-001)

  *Author: XI Wang*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 507-507*

**10 Mins**

- **Reviewer: Dr. Sushmita Rath, Medical Oncologist, Deli**
- Does the Sequence of Anthracycline and Taxane Matter? The NeoSAMBA Trial

  *Author: José Bines*
  *Citation: Oncologist. 2020 Sep;25(9):758-764*

- Inhibiting fatty acid synthase in operable triple negative breast cancer

  *Author: Sagar D. Sardesai*
  *Citation: ASCO 2020 Abstract 584*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 4, Thursday 14th January 2021

## Scientific Program

### Session 4: Triple Negative Breast Cancer

**Below 2hrs30mins video session will be available for viewing from 10.00am to 11.59pm**

**10 Mins**

**Reviewer: Dr. Mangesh Kamath, Medical Oncologist, Bangalore**

Pembrolizumab for Early Triple-Negative Breast Cancer

*Author: Peter Schmid*
*Citation: N Engl J Med 2020; 382:810-821*

Neoadjuvant atezolizumab in combination with sequential nab-paclitaxel and anthracycline-based chemotherapy versus placebo and chemotherapy in patients with early-stage triple-negative breast cancer (IMpassion031): a randomised, double-blind, phase 3 trial

*Author: Elizabeth A Mittendorf*
*Citation: Lancet. 2020 Oct 10;396(10257):1090-1100*

**10 Mins**

**Reviewer: Dr. Shruti Kate, Medical Oncologist, Nasik**

TBCRC 048: A phase II study of olaparib monotherapy in metastatic breast cancer patients with germline or somatic mutations in DNA damage response (DDR) pathway genes (Olaparib Expanded).

*Author: Nadine M. Tu*
*Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1002-100*

Effect of Adjuvant Paclitaxel and Carboplatin on Survival in Women With Triple-Negative Breast Cancer: A Phase 3 Randomized Clinical Trial

*Author: Yu, Ke-Da*
*Citation: JAMA oncology vol. 6,9 (2020): 1390-1396*

**10 Mins**

**Reviewer: Dr. Suman Karanth, Medical Oncologist, Delhi**

KEYNOTE-355: Randomized, double-blind, phase III study of pembrolizumab + chemotherapy versus placebo + chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer

*Author: Javier Cortes*
*Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1000-1000*

Additional efficacy endpoints from the phase 3 KEYNOTE-355 study of pembrolizumab plus chemotherapy vs placebo plus chemotherapy as first-line therapy for locally recurrent inoperable or metastatic triple-negative breast cancer

*Author: Hope S. Rugo*
*Citation: SABCS 2020 GS3-01*

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**15 Mins**

Reviewer: Dr. S Krupashankar, Medical Oncologist, Coimbatore

- ASCENT: A randomized phase III study of sacituzumab govitecan (SG) vs treatment of physician's choice (TPC) in patients (pts) with previously treated metastatic triple-negative breast cancer (mTNBC)

  *Author: Aditya Bardia*
  *Citation: ESMO 2020 LBA17*

- IMpassion130: Final OS analysis from the pivotal phase III study of atezolizumab + nab-paclitaxel vs placebo + nab-paclitaxel in previously untreated locally advanced or metastatic triple-negative breast cancer

  *Author: Leisha Emens*
  *Citation: ESMO 2020 LBA16*

- Primary results from IMpassion131, a double-blind placebo-controlled randomised phase III trial of first-line paclitaxel (PAC) ± atezolizumab (atezo) for unresectable locally advanced/metastatic triple-negative breast cancer (mTNBC)

  *Author: David Miles*
  *Citation: ESMO 2020 LBA15*

**10 Mins**

Reviewer: Dr. Sandip Ganguly, Medical Oncologist, Kolkata

- Final results of the double-blind placebo (PBO)-controlled randomised phase II LOTUS trial of first-line ipatasertib (IPAT) + paclitaxel (PAC) for inoperable locally advanced/metastatic triple-negative breast cancer (mTNBC)

  *Author: Rebecca Dent*
  *Citation: ESMO Breast Proffered Paper : 139O*

- Double-blind placebo (PBO)-controlled randomized phase III trial evaluating first-line ipatasertib (IPAT) combined with paclitaxel (PAC) for PIK3CA/AKT1/PTEN-altered locally advanced unresectable or metastatic triple-negative breast cancer (aTNBC): primary results from IPATunity130 Cohort A

  *Author: Dent R*
  *Citation: SABCS 2020 GS3-04*

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**Rapid Review I**

**Reviewer: Dr. Reetu Jain, Medical Oncologist, Mumbai**

- Evaluation of Triple-Negative Breast Cancer Early Detection via Mammography Screening and Outcomes in African American and White American Patients

  *Author: Yalei Chen*
  *Citation: JAMA Surg. 2020 May 1;155(5):440-442*

- Disparities in the receipt of National Comprehensive Cancer Network (NCCN) guideline adherent care in triple-negative breast cancer (TNBC) by race/ethnicity, socioeconomic status, and insurance type

  *Author: Chimezie Ubbaonu*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1080-1080*

- Treatment times in breast cancer patients receiving neoadjuvant vs adjuvant chemotherapy: Is efficiency a benefit of preoperative chemotherapy? Cancer Medicine

  *Author: Nicole M. Melchior*
  *Citation: Cancer Med 2020 Apr;9(8):2742-2751*

- GAIN-2: Neo-/adjuvant phase III trial to compare intense dose-dense chemotherapy (CT) to tailored dose-dense CT in patients (pts) with high risk early breast cancer (EBC): Results on safety and interim invasive disease-free survival (iDFS)

  *Author: Volker Moebu*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 516-516*

- Differential Benefit of Adjuvant Docetaxel-Based Chemotherapy in Patients With Early Breast Cancer According to Baseline Body Mass Index

  *Author: Christine Desmedt*
  *Citation: J Clin Oncol. 2020 Sep 1;38(25):2883-2891*

- Evaluation of Adjuvant Treatments for T1 N0 M0 Triple-Negative Breast Cancer

  *Author: Zhai, Zhen et al.*
  *Citation: JAMA network open vol. 3,11 e2021881.2 Nov. 2020*

- Addition of chemotherapy to local therapy in women aged 70 years or older with triple-negative breast cancer: a propensity-matched analysis

  *Author: Jennifer A Crozier*
  *Citation: The Lancet Oncology, VOLUME 21, ISSUE 12, P1611-1619, DECEMBER 01, 2020*

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- High-Dose Chemotherapy With Hematopoietic Stem Cell Transplant in Patients With High-Risk Breast Cancer and 4 or More Involved Axillary Lymph Nodes: 20-Year Follow-up of a Phase 3 Randomized Clinical Trial

  *Author: Tessa G Steenbruggen*
  *Citation: JAMA Oncol. 2020 Apr 1;6(4):528-534*

- Oral Paclitaxel and Encequidar (oPac+E) versus IV paclitaxel (IVPac) in the Treatment of Metastatic Breast Cancer (mBC) Patients (Study KX-ORAX-001): Progression Free Survival (PFS) and Overall Survival (OS) Updates

  *Author: Umanzor G, Rugo HS, Barrios FJ, et al*
  *Citation: SABCS 2020 PD1-08*

- Abraxane plus cisplatin compared with gemcitabine plus cisplatin as first line treatment in patients with metastatic triple negative breast cancer (GAP)/A multicenter,randomised,open-label phase III Trial

  *Author: Xichun HU*
  *Citation: Annals of oncology(2020)31(suppl_4);s348-s395*

**15 Mins**

**Rapid Review II**

**Reviewer: Dr. Amit Agarwal, Medical Oncologist, Delhi**

- Association of Germline Variant Status With Therapy Response in High-risk Early-Stage Breast Cancer: A Secondary Analysis of the GeparOcto Randomized Clinical Trial

  *Author: Esther Pohl-Rescigno*
  *Citation: JAMA Oncol. 2020 May 1;6(5):744-748*

- Evaluation of durvalumab in combination with olaparib and paclitaxel in high-risk HER2 negative stage II/III breast cancer: Results from the I-SPY 2 TRIAL

  *Author: Pusztai L*
  *Citation: Abstract No. CT011.2020 AACR.June 20-24,2020*

- Association of Event-Free and Distant Recurrence-Free Survival With Individual-Level Pathologic Complete Response in Neoadjuvant Treatment of Stages 2 and 3 Breast Cancer Three-Year Follow-up Analysis for the I-SPY2 Adaptively Randomized Clinical Trial

  *Author: Laura J Esserman*
  *Citation: JAMA Oncol. 2020;6(9):1355-1362*

- Comprehensive profiling of androgen receptor-positive (AR+) triple-negative breast cancer (TNBC) patients (pts) treated with standard neoadjuvant therapy (NAT) +/- enzalutamide

  *Author: Bora Lim*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 517-517*

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- Talazoparib versus chemotherapy in patients with germline BRCA1/2-mutated HER2-negative advanced breast cancer: final overall survival results from the EMBRACA trial

  *Author: J K Litton*
  *Citation: Ann Oncol.2020 Nov;31(11):1526-1535*

- Results of a phase II randomized trial of cisplatin +/- veliparib in metastatic triple-negative breast cancer (TNBC) and/or germline BRCA-associated breast cancer (SWOG S1416).

  *Author: Priyanka Sharma*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1001-1001*

- Veliparib plus carboplatin-paclitaxel in patients with HER2-negative advanced/metastatic gBRCA-associated breast cancer: Results in hormone receptor-positive and triple-negative breast cancer subgroups from the phase III BROCADE3 trial

  *Author: Ayoub J-P*
  *Citation: ESMO 2020 Abstract 1400*

- Veliparib with carboplatin and paclitaxel in BRCA-mutated advanced breast cancer (BROCADE3): a randomised, double-blind, placebo-controlled, phase 3 trial

  *Author: Véronique Diéras*
  *Citation: Lancet Oncol. 2020 Oct;21(10):1269-1282*

- Phase II trial of bicalutamide in combination with palbociclib for the treatment of androgen receptor (+) metastatic breast cancer

  *Author: Ayca Gucalp*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1017-1017*

**15 Mins**

**Rapid Review III**

**Reviewer: Dr. Aju Mathew, Medical Oncologist, Kochi**

- Immune phenotype and response to neoadjuvant systemic therapy (NAST) in triple negative breast cancer (TNBC).

  *Author: Clinton Yam*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 509-509*

- Randomized phase III trial of eribulin (E) versus standard weekly paclitaxel (P) as first- or second-line therapy for locally recurrent or metastatic breast cancer (MBC)

  *Author: Minetta C. Liu*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1016-1016*

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- A phase Ib/II study of eribulin (ERI) plus pembrolizumab (PEMBRO) in metastatic triple-negative breast cancer (mTNBC) (ENHANCE 1)

  *Author: Sara M. Tolaney*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1015-1015*

- Tumour infiltrating lymphocytes (TILs), PD-L1 expression and their dynamics in the NeoTRIPaPDL1 trial

  *Author: Bianchini G*
  *Citation: ESMO 2020 LBA13*

- Effect of Pembrolizumab Plus Neoadjuvant Chemotherapy on Pathologic Complete Response in Women With Early-Stage Breast Cancer: An Analysis of the Ongoing Phase 2 Adaptively Randomized I-SPY2 Trial

  *Author: Nanda R*
  *Citation: JAMA Oncol. 2020;6(5):676-684*

- Results of ENCORE 602 (TRIO025), a phase II, randomized, placebo-controlled, double-blinded, multicenter study of atezolizumab with or without entinostat in patients with advanced triple-negative breast cancer (aTNBC).

  *Author: Joyce O'Shaughnessy*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1014-1014*

- Abstract 128O 'PDL1/CD274 gain/amplification as a predictive marker of checkpoint blockade inhibitor efficacy in metastatic breast cancer: exploratory analysis of the SAFIR02-IMMUNO randomized phase II trial.'

  *Author: Thomas Bachelot*
  *Citation: Annals of Oncology, Volume 31, Supplement 2, May 2020*

- Abstract CT233: Phase Ib/II study of leronlimab (PRO 140) combined with carboplatin in CCR5+ mTNBC patients

  *Author: Massimo Cristofanilli*
  *Citation: AACR Annual Meeting 2020; April 27-28, 2020 and June 22-24, 2020*

- Capivasertib Plus Paclitaxel Versus Placebo Plus Paclitaxel As First-Line Therapy for Metastatic Triple-Negative Breast Cancer: The PAKT Trial

  *Author: Peter Schmid*
  *Citation: J Clin Oncol. 2020 Feb 10;38(5):423-433*

- Effect of Taxane Chemotherapy With or Without Indoximod in Metastatic Breast Cancer: A Randomized Clinical Trial

  *Author: Veronica Mariotti*
  *Citation: JAMA Oncol. 2020 Nov 5;e205572*

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**10 Mins**

- Highlights of Triple Negative Breast Cancer
- **Speaker: Dr. T. P. Sahoo, Medical Oncologist, Bhopal**

**5 Mins**

Introduction by **Dr. Shona Nag**

**15 Mins**

- **Reviewer: Dr. Prabhat Bhargava, Medical Oncologist, Mumbai**
- Outcome and molecular landscape of patients with PIK3CA-mutated metastatic breast cancer

  *Author: F Mosele*
  *Citation: Ann Oncol. 2020 Mar;31(3):377-386*
- Comprehensive Profiling of Poor-Risk Paired Primary and Recurrent Triple-Negative Breast Cancers Reveals Immune Phenotype Shifts

  *Author: Katherine E Hutchinson*
  *Citation: Clin Cancer Res. 2020 Feb 1;26(3):657-668*
- Metastatic Breast Cancer: TIL it is Too Late

  *Author: Peter Savas*
  *Citation: Metastatic Breast Cancer: TIL it is Too Late Clin Cancer Res. 2020 Feb 1;26(3):526-528*

**15 Mins**

- **Reviewer: Dr. Mansi Sharma, Medical Oncologist, Delhi**
- Circulating tumour DNA analysis to direct therapy in advanced breast cancer (plasmaMATCH): A multicentre, multicohort, phase 2a, platform trial

  *Author: Nicholas C Turner*
  *Citation: Lancet Oncol. 2020 Oct;21(10):1296-1308*
- Association of Circulating Tumor DNA With Disease-Free Survival in Breast Cancer: A Systematic Review and Meta-analysis

  *Author: Carolyn Cullinane*
  *Citation: JAMA Netw Open. 2020 Nov 2;3(11):e2026921*
- Clinical utility of serial circulating tumor cell (CTC) enumeration as early treatment monitoring tool in metastatic breast cancer (MBC) – A global pooled analysis with individual patient data

  *Author: Janni W*
  *Citation: SABCS 2020 GS4-08*

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**Reviewer: Dr. Vivek Agarwala, Medical Oncologist, Kolkata**

- Assessing tumour fraction of CSF cfDNA improves diagnostic accuracy and therapeutic monitoring in breast cancer leptomeningeal metastasis (BCLM)

  *Author: Amanda Fitzpatrick*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S274-S302*

- SAR439859, an oral selective estrogen receptor (ER) degrader (SERD), in ER+/ HER2- metastatic breast cancer (mBC): Biomarker analyses from a phase I/II study

  *Author: Sarat Chandarlapaty*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S348-S395*

- Pooled ctDNA analysis of the MONALEESA (ML) phase III advanced breast cancer (ABC) trials

  *Author: Fabrice Andre*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 1009-1009*

**15 Mins**

**Reviewer: Dr. Manikandan Dhanushkodi, Medical Oncologist, Chennai**

- Exploring the causal role of the human gut microbiome in breast cancer risk using mendelian randomization

  *Author: Tim Robinson*
  *Citation: SABCS 2020 GS2-06*

- Microbiome analyses of blood and tissues suggest cancer diagnostic approach

  *Author: Gregory D. Poore*
  *Citation: Nature volume 579, pages567-574(2020)*

- The human tumor microbiome is composed of tumor type-specific intracellular bacteria

  *Author: Deborah Nejman*
  *Citation: Science 29 May 2020:Vol. 368, Issue 6494, pp. 973-980*

**15 Mins**

**Reviewer: Dr. Purvi Thakkar, Surgical Oncologist, Mumbai**

- BH3 mimetics selectively eliminate chemotherapy-induced senescent cells and improve response in TP53 wild-type breast cancer

  *Author: Ashkan Shahbandi*
  *Citation: Cell Death Differ. 2020 Nov; 27(11): 3097-3116. Published online 2020 May 26*

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- Clearance of therapy-induced senescent tumor cells by the senolytic ABT-263 via interference with BCL-XL–BAX interaction

  *Author: Tareq Saleh*
  *Citation: Mol Oncol. 2020 Oct; 14(10): 2504-2519*

- Preclinical antitumor efficacy of senescence-inducing chemotherapy combined with a nanosenolytic

  *Author: Irene Galiana*
  *Citation: Journal of controlled Release 2020*

**10 Mins**

**Reviewer: Dr. M. V. Chandrakanth, Medical Oncologist, Kolkata**

- Synthetic Lethal and Resistance Interactions with BET Bromodomain Inhibitors in Triple-Negative Breast Cancer

  *Author: Shaokun Shu*
  *Citation: Mol Cell. 2020 Jun 18;78(6):1096-1113.e8*

- Targeting MYCN-expressing triple-negative breast cancer with BET and MEK inhibitors

  *Author: Johanna M. Schafer*
  *Citation: Science Translational Medicine 11 Mar 2020:Vol. 12, Issue 534, eaaw8275 DOI: 10.1126/scitranslmed.aaw8275*

**40 Mins**

**Rapid Review**

**Reviewer: Dr. Shona Nag, Medical Oncologist, tPune**

- Estrogen Receptor Pathway Activity Score to Predict Clinical Response or Resistance to Neoadjuvant Endocrine Therapy in Primary Breast Cancer

  *Author: Márcia A Inda*
  *Citation: Mol Cancer Ther. 2020 Feb;19(2):680-689*

- Mutation analysis of circulating tumour DNA from baseline and study discontinuation samples in SANDPIPER, a phase III study of taselisib or placebo with fulvestrant in oestrogen receptor-positive, human epidermal growth factor receptor 2-negative, PIK3CA-mutant advanced breast cancer16

  *Author: William Jacot*
  *Citation: ESMO breast Abstract 30*

- Molecular Drivers of Onco type DX, Prosigna, EndoPredict, and the Breast Cancer Index: A TransATAC Study

  *Author: Richard Buus*
  *Citation: J Clin Oncol. 2020 Oct 27;JCO2000853*

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- cfDNA analysis from phase I/II study of lerociclib (G1T38), a continuously dosed oral CDK4/6 inhibitor, with fulvestrant in HR+/HER2- advanced breast cancer patients

  *Author: Boris Krastev*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S348-S395. 10.1016/annonc/annonc268*

- Study Identifies UACA as a Modulator of Breast Cancer Chemoresistance, Survival

  *Author: Dr. Kushi*
  *Citation: SABCS 2020 GS2-05*

- The Genomic Landscape of Intrinsic and Acquired Resistance to Cyclin-Dependent Kinase 4/6 Inhibitors in Patients with Hormone Receptor-Positive Metastatic Breast Cancer

  *Author: Seth A Wander*
  *Citation: Cancer Discov. 2020 Aug;10(8):1174-1193*

- PTEN Loss Mediates Clinical Cross-Resistance to CDK4/6 and PI3Kα Inhibitors in Breast Cancer

  *Author: Carlotta Costa*
  *Citation: Cancer Discov. 2020 Jan;10(1):72-85.doi: 10.1158/2159-8290.CD-18-0830*

- Transcriptional Profiles and Stromal Changes Reveal Bone Marrow Adaptation to Early Breast Cancer in Association with Deregulated Circulating microRNAs

  *Author: Claudia Chiodoni*
  *Citation: Cancer Res. 2020 Feb 1;80(3):484-498*

- Tumor sequencing is useful to refine the analysis of germline variants in unexplained high-risk breast cancer families

  *Author: Cédric Van Marck*
  *Citation: Breast Cancer Res. 2020; 22: 36*

- Efficacy and Determinants of Response to HER Kinase Inhibition in HER2-Mutant Metastatic Breast Cancer

  *Author: Lillian M Smyth*
  *Citation: Cancer Discov. 2020 Feb;10(2):198-213*

- ERBB3 mRNA expression in breast cancer (BC): A SOLTI biomarker discovery analysis

  *Author: Tomas Pascual*
  *Citation: Annals of Oncology (2020) 31 (suppl_2): S15-S41. 10.1016/annonc/annonc117*

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- Defining the mutational landscape of 3,217 primary breast cancer transcriptomes through large-scale RNA-seq within the Sweden Cancerome Analysis Network: Breast Project (SCAN-B; NCT03430492).

  *Author: Christian Brueffer*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 518-518*

- Treatment persistence of residual breast tumors through an embryonic diapause-like cancer cell state with suppressed myc activity

  *Author: Eugen Dhimolea*
  *Citation: SABCS 2020 GS1-07*

- Classification of triple negative breast cancer (TNBC) by DNA damage immune response (DDIR) signature and homologous recombination deficiency

  *Author: Shane R Stecklein*
  *Citation: SABCS 2020 GS3-05*

- TRIP13 Regulates DNA Repair Pathway Choice through REV7 Conformational Change

  *Author: Connor S. Clairmont*
  *Citation: Nature Cell Biology volume 22, pages87–96(2020)*

- Increased lysosomal biomass is responsible for the resistance of triple-negative breast cancers to CDK4/6 inhibition

  *Author: Anne Fassl*
  *Citation: Science Advances 17 Jun 2020:Vol. 6, no. 25, eabb2210DOI: 10.1126/sciadv.abb2210*

- TGF-β suppresses type 2 immunity to cancer Nature

  *Author: Ming Liu*
  *Citation: 2020 Nov;587(7832):115-120. doi: 10.1038/s41586-020-2836-1*

- Cancer immunotherapy via targeted TGF-β signalling blockade in T H cells

  *Author: Shun Li*
  *Citation: Nature. 2020 Nov;587(7832):121-125. doi: 10.1038/s41586-020-2850-3*

- FOXA1 Mutations Reveal Distinct Chromatin Profiles and Influence Therapeutic Response in Breast Cancer

  *Author: Amaia Arruabarrena-Aristorena*
  *Citation: Cancer Cell. 2020 Oct 12;38(4):534-550.e9. doi: 10.1016/j.ccell.2020.08.003*

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- Circulating Tumor Cells Exhibit Metastatic Tropism and Reveal Brain Metastasis Drivers

  *Author: Remi Klotz*
  *Citation: Cancer Discov. 2020 Jan;10(1):86-103. doi: 10.1158/2159-8290.CD-19-0384*

- Quantitative proteomic landscape of metaplastic breast carcinoma pathological subtypes and their relationship to triple-negative tumors

  *Author: Sabra I Djomehri*
  *Citation: Nat Commun. 2020 Apr 7;11(1):1723*

- Functional inactivation of E-cadherin drives EMT-less metastasis

  *Author: Saverio Alberti*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S1052-S1064. 10.1016/annonc/annonc295*

### Session 6: Supportive Care

**15 Mins**

**Reviewer: Dr. Ramavath Dev, Medical Oncologist, Hyderabad**

- Long-term Cardiopulmonary Consequences of Treatment-Induced Cardiotoxicity in Survivors of ERBB2-Positive Breast Cancer

  *Author: Anthony F Yu*
  *Citation: JAMA Cardiol. 2020 Mar 1;5(3):309-317*

- CHIPing Away at Breast Cancer (AML in Breast Cancer)

  *Author: Adam S Sperling*
  *Citation: JNCI: Journal of the National Cancer Institute, Volume 112, Issue 1, January 2020, Pages 10–11*

- Association between HT and incidence of Neurodegenerative outcomes

  *Author: Branigan et al*
  *Citation: Jama Network open 2020 3(3)*

**20 Mins**

**Reviewer: Dr. Bharath Rangarajan, Medical Oncologist, Coimbatore**

- Diet-Related Metabolomic Signature of Long-Term Breast Cancer Risk Using Penalized Regression: An Exploratory Study in the SU.VI.MAX Cohort

  *Author: Lucie Lécuyer*
  *Citation: Cancer Epidemiol Biomarkers Prev. 2020 Feb;29(2):396-405.doi: 10.1158/1055-9965.EPI-19-0900. Epub 2019 Nov 25*

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- Glycemic index, glycemic load and breast cancer risk

  *Author*: Debras
  *Citation: SABCS 2020 GS2-07*

- Diabetes risk reduction diet and survival following breast cancer

  *Author*: *Wang*
  *Citation: SABCS 2020 GS2-09*

- Dietary Modification and Breast Cancer Mortality: Long-Term Follow-Up of the Women's Health Initiative Randomized Trial

  *Author*: *Rowan T Chlebowski*
  *Citation: J Clin Oncol. 2020 May 1;38(13):1419-1428*

**15 Mins**

- **Reviewer: Dr. Smita Saldanha**

- A pragmatic cluster-randomized trial of ambulatory toxicity management in patients receiving adjuvant or neo-adjuvant chemotherapy for early stage breast cancer (AToM)

  *Author*: *Monika Krzyzanowska*
  *Citation: Annals of Oncology (2020) 31 (suppl_4): S1142-S1215*

- Distance to treatment a burden for rural BC patients

  *Author*: *Longacre et al*
  *Citation: Journal of Rural Health*

- How Long Do I Have? New Online Tool for Patients With Cancer

  *Author*: *Roxanne Nelson*

**15 Mins**

- **Reviewer: Dr. Pritam Kataria**

- Use of hormone replacement therapy and risk of breast cancer: nested case-control studies using the QResearch and CPRD databases

  *Author*: *Yana Vinogradova*
  *Citation: BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m3873 (Published 28 October 2020)*

- Proton Pump Inhibition and cognition in BC survivors

  *Author*: *Madison et al*
  *Citation: J of Cancer Survivorship Asco Post 21/1/2020*

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# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 5, Friday 15th January 2021

## Scientific Program

### Session 6: Supportive Care

**Below 4hrs video session will be available for viewing from 10am to 11.59pm**

Patient-Reported Cognitive Impairment Among Women With Early Breast Cancer Randomly Assigned to Endocrine Therapy Alone Versus Chemoendocrine Therapy: Results From TAILORx

*Author: Lynne I. Wagner*
*Citation: J Clin Oncol 2020 Jun 10;38(17):1875-1886*

**15 Mins**

**Reviewer: Dr. Annu Susan George, Medical Oncologist, Kochin**

Spironolactone use does not increase the risk of female breast cancer recurrence: A retrospective analysis

*Author: Chapman Wei*
*Citation: Journal of the American Academy of Dermatology, S0190-9622(20)30950-6*

Targeting depressive symptoms in younger breast cancer survivors

*Author: Ganz*
*Citation: SABCS 2020 GS2-10.*

Chances of pregnancy after breast cancer, reproductive and disease outcomes: A systematic review and meta-analysis

*Author: Lambertini*
*Citation: SABCS 2020 GS3-09*

**15 Mins**

**Rapid Review**

**Reviewer: Dr. Bhawna Sirohi, Medical Oncologist, Chennai**

Olanzapine 5 mg plus standard antiemetic therapy for the prevention of chemotherapy-induced nausea and vomiting (J-FORCE): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial

*Author: Hironobu Hashimoto*
*Citation: Lancet Oncol. 2020 Feb;21(2):242-249*

Alcohol Consumption, Cigarette Smoking, and Risk of Breast Cancer for BRCA1 and BRCA2 Mutation Carriers: Results from The BRCA1 and BRCA2 Cohort Consortium

*Author: Hongyan Li*
*Cancer Epidemiol Biomarkers Prev. 2020 Feb;29(2):368-378*

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- Hippocampal Avoidance During Whole-Brain Radiotherapy Plus Memantine for Patients With Brain Metastases: Phase III Trial NRG Oncology CC001

  *Author: Paul D Brown*
  *Citation: J Clin Oncol. 2020 Apr 1;38(10):1019-1029*

- Fiber consumption and breast cancer incidence: A systematic review and meta-analysis of prospective studies

  *Author: Maryam S Farvid*
  *Citation: Cancer. 2020 Jul 1;126(13):3061-3075*

- Physical activity before, during and after chemotherapy for high-risk breast cancer: relationships with survival

  *Author: Rikki A Cannioto*
  *Citation: J Natl Cancer Inst. 2020 Apr 2;djaa046*

- Myocardial infarction accelerates breast cancer via innate immune reprogramming

  *Author: Graeme J Koelwyn*
  *Citation: Nat Med. 2020 Sep;26(9):1452-1458*

- Increased Acid-Producing Diet and Past Smoking Intensity Are Associated with Worse Prognoses Among Breast Cancer Survivors: A Prospective Cohort Study

  *Author: Tianying Wu*
  *Citation: J Clin Med. 2020 Jun 11;9(6):1817*

- A geriatric assessment (GA) intervention to reduce treatment toxicity in older patients with advanced cancer: A University of Rochester Cancer Center NCI community oncology research program cluster randomized clinical trial (CRCT).

  *Author: Supriya Gupta Mohile*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 12009-12009*

- Effects of YOCAS yoga, cognitive behavioral therapy, and survivorship health education on insomnia: A URCC NCORP Research Base Phase III RCT in 740 cancer survivors

  *Author: Karen Michelle Mustian*
  *Citation: Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 12005-12005*

- Are We Ready to Use Teriparatide to Treat Medication-Related Osteonecrosis of the Jaw in Clinical Practice?

  *Author: Carla I. Ripamonti*
  *Citation: Journal of Clinical Oncology 38, no. 26 (September 10, 2020) 2949-2951*

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Day 5

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- Should Body Mass Index Guide the Choice of Chemotherapy in Patients With Breast Cancer?

  *Author: Kristen Whitaker*
  *Citation: ASCO post Oct. 25th 2020*

- Randomized trial of a collaborative palliative and oncology care intervention to improve communication about end-of-life care in patients with metastatic breast cancer

  *Author: Jennifer S. Temel, MD*
  *Citation: ASCO 2020 Abstract 1008*

- Chemotherapy use near the end-of-life in patients with metastatic breast cancer

  *Author: Luisa Edman Kessler*
  *Citation: Breast Cancer Res Treat. 2020 Jun;181(3):645-651*

- Long-term patient reported outcomes (PRO) and hematologic toxicity among patients (pts) who received granulocyte-colony stimulating factors (G-CSF) during chemotherapy (CT) for early breast cancer (EBC)

  *Author: P. Lapidari*
  *Citation: j.annonc.2020.08.1464*

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Day 5

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 6, Saturday 16th January 2021

## Scientific Program

### Session 7 Keynote & Panel Discussion

### International Keynote & Panel Discussion

**09.00am - 09.30am**

**Chairpersons: Dr. K Pavithran, Dr. D C Doval**

Recent advances in management of HER2 +ve Breast Cancer
**Speaker: Dr. Shanu Modi**

**09.30am - 10.20am**

Panel Discussion : HER2 Positive breast cancer

Moderator: Dr. Prasad Narayanan
Panelists: Dr. Atul Batra, Dr. Amit Agarwal, Dr. Tejinder Singh, Dr. Chetan Deshmukh, Dr. Amol Patel, Dr. Amol Dongre, Dr. Bharat Bhosale, Dr. Anubha Bharthuar

**10.20am - 10.50am**

**Chairpersons: Dr. Dhairyasheel Savant, Dr. Shailesh Talati**

HR+ve Breast Cancer : Past, Present and future
**Speaker: Dr. Shaheenah Dawood**

**10.50am - 11.40am**

Panel discussion : HR+ve breast cancer

Moderator: Dr. Senthil Rajappa
Panelists: Dr. T P Sahoo, Dr. Niti Raizada, Dr. Avinash Pandey, Dr. Krishna Prasad, Dr. Ashish Bakshi, Dr. Poonam Patil, Dr. Bhavana Parikh, Dr. Lalit Mohan Sharma, Dr. Ghanshyam Biswas, Dr. Rakesh Roy

**11.40am - 12.10pm**

**Chairpersons: Dr. Ramesh Nimaggada, Dr. Madhuchanda Kar**

Translational Science in Breast Cancer
**Speaker: Dr. Sherene Loi**

**12.10pm - 12:40pm**

**Chairpersons: Dr. Shekhar Salkar, Dr. Sanjay Sharma**

Surgical management post neoadjuvant systemic therapy in breast cancer - Special focus on the axilla
**Speaker: Dr. Ashutosh Kothari**

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Day 6

# 6th YEAR IN REVIEW BREAST CANCER

The year that was...2020

**11th - 16th JAN 2021**

## Day 6, Saturday 16th January 2021

## Session 7 Keynote & Panel Discussion

### International Keynote & Panel Discussion

**12.40pm - 01.30pm**

Panel Discussion : Loco-regional Breast Cancer

Moderator: Dr. Sanjoy Chatterjee
Panelists: Dr. Anupama Mane, Dr. Kanchan Kaur, Dr. Selvi Radhakrishna, Dr. Gautam Sharan, Dr. Sapna Nangia, Dr. Jayant Vaidya, Dr. Tabassum W., Dr. Sidharth Sahni, Dr. Monica Malik

**01.30pm - 02.00pm**

**Chairpersons: Dr. Asha Kapadia, Dr. Shyam Agarwal**

Triple Negative Breast Cancer - From platinum to targeted approaches: Have we made any progress?

**Speaker: Dr. Rebecca Dent**

**02.00pm - 02:50pm**

Panel discussion : Triple Negative Breast Cancer

Moderator: Dr. B K Smruti
Panelists: Dr. T Raja, Dr. Ajay Bapna, Dr. Anita Ramesh, Dr. Meenu Walia, Dr. Manisha Singh, Dr. Nirmal Raut, Dr. Vashistha Maniar, Dr. Ashish Singh, Dr. Shailesh Bondarde, Dr. Amit Verma

**02:50pm - 03:10pm**

Did you know?

**Speaker: Dr. Sudeep Gupta**

**03:10pm - 03:20pm**

**Vote of thanks by Dr. Shona Nag & Dr. Sudeep Gupta**

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# 6th YEAR IN REVIEW
# BREAST CANCER

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**11th - 16th JAN 2021**

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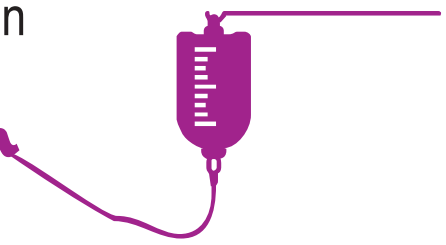
For chemotherapy induced **Iron Deficiency Anemia**

# Encicarb™ 1K

Ferric Carboxymaltose1000 mg/20 ml Injection

*Closest to IDEAL I.V Iron*



## Minimal Hypersensitivity

No test dose recommended

## Advantage of giving Full Required Dose*

1000 mg iron can be given in a single dose

## Convenient IV infusion of 15 minutes and flexible dosing**

Up to 200 mg as a IV bolus injection

Up to 1000 mg as a rapid IV infusion in just 15 minutes

Reference: 1. Hedenus M, Karlsson T, Ludwig H, Rzychon B, Felder M, Roubert B, et al. Intravenous iron alone resolves anemia in patients with functional iron deficiency and lymphoid malignancies undergoing chemotherapy. Medical Oncology. 2014Jun; 31(12).

*Data on file ** Encicarb prescribing information

CIA: Chemotherapy-induced Anemia; FID: Functional Iron Deficiency; FCM: Ferric Carboxymaltose ESA: Erythropoiesis-stimulating Agent Hb: Hemoglobin

## Abridged Prescribing Information

**ENCICARB INJECTION**

**Composition:** Each ml contains Ferric Carboxymaltose equivalent to elemental Iron 50 mg. **Presentation:** Vials of 20 ml. For further details, please consult the full prescribing information. **Indications:** For treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. Dosage: The cumulative dose for repletion of iron using ferric carboxymaltose is determined based on the patient's body weight and haemoglobin (Hb) level and must not be exceeded. For Hb <10 g/dl - body weight 35 kg to <70 kg: 1500 mg, body weight ≥70 kg: 2000 mg. For Hb >10 g/dl - body weight 35 kg to <70 kg: 1000 mg, body weight ≥70 kg: 1500 mg. A cumulative iron dose of 500 mg should not be exceeded for patients with body weight < 35 kg. For overweight patients, a normal body weight/blood volume relation should be assumed when determining the iron requirement. Maximum tolerated single dose: 1000 mg of iron (20 ml) per day or 15 mg of iron (0.3 ml) per kg body weight. Do not administer 1000 mg of iron (20 ml) more than once a week. **Intravenous injection:** Undiluted solution up to 1000 mg iron. For doses greater than 200 and up to 500 mg iron, ferric carboxymaltose should be administered at a rate of 100 mg/min. For doses greater than 500 and up to 1000 mg iron, ferric carboxymaltose should be administered over 15 minutes. **Intravenous drip infusion:** Intravenous infusion up to a maximum single dose of 20 ml of Ferric Carboxymaltose Injection (1000 mg of iron). Ferric Carboxymaltose Injection must be diluted only in sterile 0.9% sodium chloride solution. A single maximum daily injection dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients. **Contra-indications:** Contraindicated in cases of known hypersensitivity to Ferric Carboxymaltose Injection or to any of its excipients, anaemia not attributed to iron deficiency (e.g. other microcytic anaemia), evidence of iron overload or disturbances in utilization of iron, and in pregnancy in the first trimester. **Adverse reactions:** Headache, dizziness, nausea, abdominal pain, constipation, diarrhea, injection site reactions and rash are commonly reported adverse reactions. **Use in special population:** Pregnancy: A careful risk/benefit evaluation is required before use during pregnancy. Use during pregnancy may influence skeletal development in the fetus. **Lactation:** Based on limited data on nursing women it is unlikely that Ferric Carboxymaltose Injection represents a risk to the nursing child. **Overdosage:** May lead to accumulation of iron in storage sites eventually leading to haemosiderosis. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation.

# MORE LIFE *with*

# KRYXANA®

ribociclib

**The only CDK 4/6 inhibitor proven to deliver consistently superior Overall Survival in HR+, HER-2 ABC*[1,2]**

**Irrespective of menopausal status[1,2]**

**Effective with any endocrine partner£[1,2]**

**Irrespective of the line of therapy#[1,3,4]**

**CDK:** Cyclin Dependent Kinase; **HR:** Hormone Receptor; **HER2:** Human Epidermal Growth Factor Receptor 2; **ABC:** Advanced Breast Cancer.
£ AI or Fulvestrant; Kryxana is not recommended for use in combination with tamoxifen; # 1st line/ 2nd line; * Superior overall survival was established in the MONALEESA-7 trial comparing Kryxana + endocrine therapy vs. placebo + endocrine therapy and in the MONALEESA-3 trial comparing Kryxana + Fulvestrant vs. Placebo + Fulvestrant.

**References:**
**1.** Data on file. Novartis Pharma AG. **2.** Im SA, et al. NEJM 2019;381:307-316. **3.** Salmon DJ, et al. Overall Survival Results from the phase III MONALEESA -3 study of Fulvestrant and Ribociclib in post menopausal patients with HR+/HER2- Advanced breast cancer. Presented at ESMO 2019. **4.** Tripathy D, et al. Lancet Oncol 2018;19(7):904-915.

Basic Succinct Statement
Kryxana ®

**Presentation:** Film-coated tablets (FCT) containing 200 mg of ribociclib. **Indications:** Kryxana is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER-2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. **Dosage and administration: Adults:** The recommended dose of Kryxana is 600 mg (3 x 200 mg FCT) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. **Special populations:** ♦Renal impairment: Mild or moderate: No dose adjustment is necessary. Severe: Starting dose of 200 mg is recommended. ♦Hepatic impairment: Mild: No dose adjustment is necessary. Moderate or severe: Dose adjustment is required, and the starting dose of 400 mg is recommended. ♦Geriatrics (≥65 years): No dose adjustment is required. ♦Pediatrics: Safety and efficacy have not been established. **Contraindications:** ♦Patients with hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** ♦Neutropenia was most frequently reported. A complete blood count (CBC) should be performed before initiating therapy. CBC should be monitored every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles then as clinically indicated. Febrile neutropenia was reported in 1.4% of patients exposed to Kryxana in the phase III clinical study. Based on the severity of the neutropenia, Kryxana may require dose interruption, reduction, or discontinuation. ♦Increases in ALT and AST have been reported, with the majority of them without concurrent elevations of bilirubin. Concurrent elevations of ALT or AST >3 x ULN and of total bilirubin >2 x ULN, with normal alkaline phosphatase levels and no cholestasis occurred in6 patients (4 patients in Study A2301, whose levels recovered to normal within 154 days; and 2 patients in Study F2301, whose levels recovered to normal within 121 and 532 days, respectively, after discontinuation of Kryxana. Liver function tests (LFTs) should be performed before initiating therapy with Kryxana. LFTs should be monitored every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, then as clinically indicated. Based on the severity of transaminase elevations, Kryxana may require dose interruption, reduction, or discontinuation. ♦QT interval prolongation has been reported with Kryxana. The use of Kryxana should be avoided in patients who have already or who are at significant risk of developing QTc prolongation. The ECG should be assessed prior to initiation of treatment. Treatment with Kryxana should be initiated only in patients with QTcF values <450 msec. The ECG should be repeated at approximately Day 14 of the first cycle and at the beginning of the second cycle, then as clinically indicated. Appropriate monitoring of serum electrolytes (including potassium, calcium, phosphorous, and magnesium) should be performed prior to initiation of treatment, at the beginning of the first 6 cycles, and then as clinically indicated. Any abnormality should be corrected before the start of Kryxana therapy. Based on the observed QT prolongation during treatment, Kryxana may require dose interruption, reduction, or discontinuation. Based on the E2301 QTcF interval data, Kryxana is not recommended for use in combination with tamoxifen. **Pregnancy, lactation, females and males of reproductive potential: Pregnancy:** It is possible that Kryxana can cause fetal harm when administered to a pregnant woman. The patient should be advised of the risk to a fetus if Kryxana is used during pregnancy or if the patient becomes pregnant while taking Kryxana. **Lactation:** A decision should be made whether to discontinue nursing or to discontinue Kryxana, taking into account the importance of Kryxana to the mother. It is recommended that women taking Kryxana should not breastfeed for at least 21 days after the last dose. **Females and males of reproductive potential:** ♦Pregnancy testing: For females of reproductive potential the pregnancy status should be verified prior to initiating treatment with Kryxana. ♦Contraception: Sexually active females of reproductive potential should use effective contraception (methods that result in < 1 % pregnancy rates) when using Kryxana during treatment and for 21 days after stopping treatment with Kryxana. ♦Infertility: Based on animal studies, Kryxana may impair fertility in males of reproductive potential. **Adverse drug reactions: Very common (≥10%):** Infections, neutropenia, leukopenia, anaemia, decreased appetite, headache, dizziness, dysgeusia, dyspnoea, cough, back pain, nausea, diarrhoea, vomiting, constipation, stomatitis, abdominal pain, alopecia, rash, pruritus, fatigue, peripheral oedema, asthenia, pyrexia, abnormal liver function tests, leukocyte count decreased, neutrophil count decreased, haemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, phosphorous decreased, Gamma-glutamyl transferase increased, albumin decreased, glucose serum decreased. **Common (1 to 10%):** lymphopenia, thrombocytopenia, febrile neutropenia, lacrimation increased, dry eye, hypocalcaemia, hypokalaemia, hypophosphataemia, vertigo, syncope, dysgeusia, dyspepsia, hepatotoxicity, erythema, dry skin, vitiligo, dry mouth, oropharyngeal pain, peripheral oedema, electrocardiogram QT prolonged, potassium decreased, bilirubin increased. **Interactions:** ♦Concomitant use of strong CYP3A inhibitors should be avoided, including but not limited to clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir, ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, verapamil, and voriconazole. Alternative medications with less potential to inhibit CYP3A should be considered. Patients should be monitored for ADRs. If concomitant use of a strong CYP3A inhibitor cannot be avoided, the Kryxana dose should be reduced to 200 mg. Grapefruit or grapefruit juice should be avoided. ♦Concomitant use of strong CYP3A inducers should be avoided, including but not limited to phenytoin, rifampin, carbamazepine and St John's Wort (Hypericum perforatum). An alternative medication with no or minimal potential to induce CYP3A should be considered. ♦Caution is advised when Kryxana is administered with CYP3A substrates with narrow therapeutic index (including but not limited to alfentanil, cyclosporine, dihydroergotamine, ergotamine, everolimus, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus), and their dose may need to be reduced. ♦Co-administration of Kryxana with medications with known potential to prolong the QT interval should be avoided such as anti-arrhythmic medicines (including but not limited to amiodarone, disopyramide, procainamide, quinidine, and sotalol), other medicinal products known to prolong the QT interval including but not limited to chloroquine, halofantrine, clarithromycin, ciprofloxacin, levofloxacin and azithromycin haloperidol, methadone, moxifloxacin, bepridil, pimozide, and ondansetron (i.v). Kryxana is not recommended for use in combination with tamoxifen. **Packs:** Kryxana strip of 21 film coated tablets

Before prescribing, please consult full prescribing information available from Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India.
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# MORE LIFE *with*

# KRYXANA®

ribociclib

**The only CDK 4/6 inhibitor proven to deliver consistently superior Overall Survival in HR+, HER-2 ABC*[1,2]**

## Pre-/Perimenopausal Women

### MONALEESA-7[1]

**~70% was the survival rate with KRYXANA+AI at 42 months£**

## Postmenopausal Women

### MONALEESA-3[2]

**~58% was the survival rate with KRYXANA + Fulvestrant at 42 months#**

**CDK:** Cyclin Dependent Kinase; **AI:** Aromatase Inhibitor; **HR:** Hormone Receptor; **HER2:** Human Epidermal Growth Factor Receptor 2; **ABC:** Advanced Breast Cancer.
* Superior overall survival was established in the MONALEESA-7 trial comparing Kryxana + endocrine therapy vs. placebo + endocrine therapy and in the MONALEESA-3 trial comparing Kryxana + Fulvestrant vs. Placebo + Fulvestrant;
£ compared to Placebo + AI = 43.0%; # compared to Placebo+ Fulvestrant = 45.9%

**References:**
**1.** Im SA, et al. NEJM 2019;381:307-316. **2.** Salmon DJ, et al. Overall Survival Results from the phase III MONALEESA -3 study of Fulvestrant and Ribociclib in post menopausal patients with HR+/HER2- Advanced breast cancer. Presented at ESMO 2019.

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Treatment with Kryxana should be initiated only in patients with QTcF values <450 msec. The ECG should be repeated at approximately Day 14 of the first cycle and at the beginning of the second cycle, then as clinically indicated. Appropriate monitoring of serum electrolytes (including potassium, calcium, phosphorous, and magnesium) should be performed prior to initiation of treatment, at the beginning of the first 6 cycles, and then as clinically indicated. Any abnormality should be corrected before the start of Kryxana therapy. Based on the observed QT prolongation during treatment, Kryxana may require dose interruption, reduction, or discontinuation. Based on the E2301 QTcF interval data, Kryxana is not recommended for use in combination with tamoxifen. **Pregnancy, lactation, females and males of reproductive potential: Pregnancy:** It is possible that Kryxana can cause fetal harm when administered to a pregnant woman. The patient should be advised of the risk to a fetus if Kryxana is used during pregnancy or if the patient becomes pregnant while taking Kryxana. **Lactation:** A decision should be made whether to discontinue nursing or to discontinue Kryxana, taking into account the importance of Kryxana to the mother. It is recommended that women taking Kryxana should not breastfeed for at least 21 days after the last dose. **Females and males of reproductive potential:** ♦Pregnancy testing: For females of reproductive potential the pregnancy status should be verified prior to initiating treatment with Kryxana. ♦Contraception: Sexually active females of reproductive potential should use effective contraception (methods that result in < 1 % pregnancy rates) when using Kryxana during treatment and for 21 days after stopping treatment with Kryxana. ♦Infertility: Based on animal studies, Kryxana may impair fertility in males of reproductive potential. **Adverse drug reactions: Very common (≥10%):** Infections, neutropenia, leukopenia, anaemia, decreased appetite, headache, dizziness, dyspnoea, cough, back pain, nausea, diarrhoea, vomiting, constipation, stomatitis, abdominal pain, alopecia, rash, pruritus, fatigue, peripheral oedema, asthenia, pyrexia, abnormal liver function tests, leukocyte count decreased, neutrophil count decreased, haemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, phosphorous decreased, Gamma-glutamyl transferase increased, albumin decreased, glucose serum decreased. **Common (1 to 10%):** lymphopenia, thrombocytopenia, febrile neutropenia, lacrimation increased, dry eye, hypocalcaemia, hypokalaemia, hypophosphataemia, vertigo, syncope, dysgeusia, dyspepsia, hepatotoxicity, erythema, dry skin, vitiligo, dry mouth, oropharyngeal pain, peripheral oedema, electrocardiogram QT prolonged, potassium decreased, bilirubin increased. **Interactions:** ♦Concomitant use of strong CYP3A inhibitors should be avoided, including but not limited to clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir, ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, verapamil, and voriconazole. Alternative medications with less potential to inhibit CYP3A should be considered. Patients should be monitored for ADRs. If concomitant use of a strong CYP3A inhibitor cannot be avoided, the Kryxana dose should be reduced to 200 mg. Grapefruit or grapefruit juice should be avoided. ♦Concomitant use of strong CYP3A inducers should be avoided, including but not limited to phenytoin, rifampin, carbamazepine and St John's Wort (Hypericum perforatum). An alternative medication with no or minimal potential to induce CYP3A should be considered. ♦Caution is advised when Kryxana is administered with CYP3A substrates with narrow therapeutic index (including but not limited to alfentanil, cyclosporine, dihydroergotamine, ergotamine, everolimus, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus), and their dose may need to be reduced. ♦Co-administration of Kryxana with medications with known potential to prolong the QT interval should be avoided such as anti-arrhythmic medicines (including but not limited to amiodarone, disopyramide, procainamide, quinidine, and sotalol), other medicinal products known to prolong the QT interval including but not limited to chloroquine, halofantrine, clarithromycin, ciprofloxacin, levofloxacin and azithromycin haloperidol, methadone, moxifloxacin, bepridil, pimozide, and ondansetron (i.v). Kryxana is not recommended for use in combination with tamoxifen.
**Packs:** Kryxana strip of 21 film coated tablets

Before prescribing, please consult full prescribing information available from Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India.
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For the use of only registered medical practitioners or a hospital or a laboratory.
India BSS dtd 7 Oct 19 based on international BSS dtd 9 Jul 18 effective from 10 Oct 19.

Issued as a Scientific Service to Healthcare Professionals:

NOVARTIS

**Novartis Healthcare Pvt. Ltd.**
**Inspire BKC, Part of 601 and 701, Bandra - Kurla Complex, Bandra (East), Mumbai - 400 051, Maharashtra, India.**
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KRYXANA OS standee 2/ ONCO/KRYXANA/1260944/31-10-2019


**~2X mPFS[1,2]**

- 11.0 months median PFS with PIVIKTO + fulvestrant vs 5.7 months with placebo + fulvestrant in patients with a PIK3CA mutation

**>2X THE RESPONSE RATE[1,2]**

- 35.7% ORR with PIVIKTO + fulvestrant vs 16.2% with placebo + fulvestrant in patients with a PIK3CA mutation who had a measurable disease

**TUMOUR SHRINKAGE**

- 3 out of 4 patients with a PIK3CA mutation had tumour shrinkage[3]

**aBC:** advanced Breast Cancer, **PIK3CA:** Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha, **PFS:** Progression Free Survival, **ORR:** Overall Response Rate.

**REFERENCES: 1.** Alpelisib Core Data Sheet: Version 1.0. Novartis Pharma AG; November 2018, **2.** André F, Ciruelos E, Rubouszky G, et al. Alpelisib for PIK3CAmutated, hormone receptor-positive advanced breast cancer. N Engl J Med. 2019;380(20):1929-1940, **3.** Data on file. Novartis Pharmaceuticals Corp; 2018.

## BASIC SUCCINCT STATEMENT (BSS)

**PIVIKTO®**

**PRESENTATION:** Film-coated tablets (FCT) containing 50mg, 150mg and 200mg of alpelisib.

**INDICATIONS:** Alpelisib is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

**DOSAGE AND ADMINISTRATION:**

**ADULTS:** The recommended dose of alpelisib is 300 mg taken orally, once daily on a continuous basis. Alpelisib should be taken immediately following food, at approximately same time each day. If a dose of alpelisib is missed, it can be taken up to 9 hours after the time it is normally administered. After more than 9 hours, the dose should be skipped for that day. On the next day, alpelisib should be taken at its usual time.If patient vomits after taking the alpelisib dose, the patient should not take an additional dose on that day, and should resume the usual dosing schedule the next day, at the usual time.

**SPECIAL POPULATIONS:** • *Renal impairment:* Mild or moderate: No dose adjustment is necessary. • *Severe:* Caution is recommended. • *Hepatic impairment:* Mild, moderate or severe: No dose adjustment is necessary. • *Geriatrics (≥65 years):* No dose adjustment is required. • *Pediatrics (≤18 years):* Safety and efficacy have not been established.

**CONTRAINDICATIONS:** • Patients with hypersensitivity to the active substance or to any of the excipients.

**WARNINGS AND PRECAUTIONS:** • **Hypersensitivity (including anaphylactic reaction):** Serious hypersensitivity reactions (including anaphylactic reaction and anaphylactic shock), manifested by symptoms including, but not limited to, dyspnea, flushing, rash, fever or tachycardia were reported in patients treated with alpelisib in clinical studies. Alpelisib should be permanently discontinued and should not be re-introduced in patients with serious hypersensitivity reactions. Appropriate treatment should be promptly initiated. • **Severe cutaneous reactions:** Cases of severe cutaneous reactions, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM) and drug reaction with eosinophilia and systemic symptoms (DRESS) were reported in patients treated with alpelisib.Alpelisib treatment should not be initiated in patients with history of severe cutaneous reactions. Patients should be advised of the signs and symptoms of severe cutaneous reactions. If symptoms or signs of severe cutaneous reactions are present, alpelisib should be interrupted until the etiology of the reaction has been determined. A consultation with dermatologist is recommended. If a severe cutaneous reaction is confirmed, alpelisib should be permanently discontinued. Alpelisib should not be reintroduced in patients who have experienced previous severe cutaneous reactions. • **Hyperglycaemia:** Hyperglycaemia was reported in of patients treated with alpelisib in the phase III clinical study. Patients with poor glycemic control may be at a higher risk of developing severe hyperglycaemia and associated complications (e.g. ketoacidosis). Patients should be advised of the signs and symptoms of hyperglycaemia. Based on the severity of the hyperglycaemia, alpelisib may require treatment interruption, dose reduction, or treatment discontinuation. • **Pneumonitis:** Pneumonitis including serious cases of pneumonitis/acute interstitial lung disease have been reported in alpelisib treated patients in clinical studies. Patients should be advised to promptly report any new or worsening respiratory symptoms. In patients who have new or worsening respiratory symptoms or are suspected to have developed pneumonitis, alpelisib treatment should be interrupted immediately and the patient should be evaluated for pneumonitis. A diagnosis of non-infectious pneumonitis should be considered. Alpelisib should be permanently discontinued in all patients with confirmed pneumonitis.

**PREGNANCY, LACTATION, FEMALES AND MALES OF REPRODUCTIVE POTENTIAL:** • **Pregnancy:** It is possible that alpelisib can cause fetal harm when administered to a pregnant woman. Alpelisib should not be used during pregnancy unless the benefits to the mother outweigh the risk to the fetus. If alpelisib is used during pregnancy, the patient should be advised of the potential risk to the fetus. • **Lactation:** Women should not breast-feed during treatment and for at least 4 days after the last dose of alpelisib. • **Females and males of reproductive potential:** • *Pregnancy testing:* For female patients of reproductive potential, the pregnancy status should be verified, prior to initiating treatment with alpelisib. • *Contraception:* Sexually active females of reproductive potential (ORP) should use effective contraception and male patients with female partners ORP should use condoms during treatment with alpelisib and for 4 days after stopping treatment with alpelisib. • *Infertility:* Based on animal studies, alpelisib may impair fertility in females and males of reproductive potential.

**ADVERSE DRUG REACTIONS:** • **Very common (≥10%):** Anaemia, diarrhoea, nausea, vomiting, stomatitis, abdominal pain, dyspepsia, fatigue, mucosal inflammation, oedema peripheral, pyrexia, mucosal dryness, urinary tract infection, weight decreased,blood creatinine increased, hyperglycaemia, decreased appetite, headache, dysgeusia, rash, alopecia, pruritus, dry skin, activated partial thromboplastin time increased, hemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, albumin decreased, calcium corrected decreased, gamma-glutamyl transferase increased, glucose plasma increased, glucose plasma decreased, lipase increased. • **Common (≥1 to <10%):** Lymphopenia, thrombocytopenia, vision blurred, dry eye, toothache, cheilitis, gingival pain, gingivitis, oedema, hypersensitivity, glycosylated hemoglobin increased, hypokalemia, hypocalcaemia, dehydration, muscle spasms, myalgia, osteonecrosis of jaw, insomnia, acute kidney injury, pneumonitis, erythema, dermatitis, palmar-plantar erythrodysaesthesia syndrome, erythema multiforme, hypertension, lymphoedema, potassium decreased, magnesium decreased. • **Uncommon (≥0.1 to <1%):** Pancreatitis, ketoacidosis, Stevens-Johnson syndrome (SJS). • **Adverse drug reactions from post-marketing experience (frequency not known):** Drug reaction with eosinophilia and systemic symptoms (DRESS).

**Description of select ADRs and treatment recommendations, where applicable:** • **Rash:** Topical corticosteroid treatment should be initiated at the first signs of rash and oral corticosteroids should be considered for more moderate to severe rashes. Additionally, antihistamines are recommended to manage symptoms of rash. Oral antihistamines may be initiated prophylactically, at the time of initiation of treatment with alpelisib. • **Gastrointestinal (GI) toxicity (nausea, diarrhoea, vomiting):** Severe diarrhoea and clinical consequences, such as dehydration and acute kidney injury have been reported during treatment with alpelisib and resolved with appropriate intervention. Patients should be managed according to local standard of care medical management, including electrolyte monitoring, administration of anti-emetics and antidiarrhoeal medications and/or fluid replacement and electrolyte supplements, as clinically indicated.

**Interactions:** • **BCRP (breast cancer resistance protein) inhibitors:** Caution is advised when co-administering alpelisib with a BCRP inhibitor (e.g. eltrombopag, lapatinib, pantoprazole), as inhibition of BCRP may lead to an increase in systemic exposure of alpelisib. • **CYP3A4 substrates:** Caution is recommended when alpelisib is used in combination with CYP3A4 substrates that also possess an additional time-dependent inhibition and induction potential on CYP3A4 that affects their own metabolism (e.g. rifampicin, ribociclib, encorafenib). • **CYP2C9 substrates with narrow therapeutic index:** No dose adjustment of alpelisib is required. However, in the absence of clinical data, caution is recommended when Alpelisib is co-administered with drugs that are CYP2C9 substrates with narrow therapeutic window (e.g.warfarin). • **CYP2B6 sensitive substrates with narrow therapeutic index:** Sensitive CYP2B6 substrates (e.g. bupropion) or CYP2B6 substrates with a narrow therapeutic window should be used with caution in combination with alpelisib, as may reduce the clinical activity of such drugs. • **Hormonal contraceptives:** It is currently unknown whether alpelisib may reduce the effectiveness of systemically acting hormonal contraceptives.

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For the use of only Oncologist.

**INDIA BSS DTD 22 OCT 2020 BASED ON INTERNATIONAL BSS DTD 13 JAN 2020 EFFECTIVE FROM 3 DEC 2020.**

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**MORE LIFE**
**To Every Moment**

PERJETA® pertuzumab

Herceptin® trastuzumab

# DUAL HER2 BLOCKADE. PROVEN SYNERGY.

NEW INDICATION

Kadcyla®

TRANSFORM THE MOMENT

**WARNING: Preparation shall be supplied against the prescription of a Cancer Specialist**

ABRIDGED PRESCRIBING INFORMATION
**Herclon™ SUMMARY OF PRESCRIBING INFORMATION**
**Generic Name: Trastuzumab for Injection**
**Brand Name: Herclon™**
**Composition:** *Active Ingredient:* Trastuzumab 150 mg single dose vials and 440 mg multidose vial containing powder for concentrate for solution for infusion. Reconstituted Herclon™ concentrate contains 21 mg/mL of trastuzumab. **Indications:** Herclon™ is indicated for *Metastatic Breast Cancer (MBC):* (i) Herclon™ is indicated for the treatment of patients with Metastatic Breast Cancer who have tumors that overexpress Human Epidermal Growth factor receptor 2 (HER2) (ii) in combination with aromatase inhibitor for the treatment of patients with HER2 positive and hormone receptor positive metastatic breast cancer. *Early Breast Cancer (EBC):* Herclon™ is indicated for the treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). Herclon™ is also indicated for adjuvant treatment of HER2 over-expressing node positive or high risk node negative breast cancer (a) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel (b) with docetaxel and carboplatin. Herclon™ is also indicated for treatment of patients with HER2 positive early breast cancer in combination with neoadjuvant chemotherapy followed by adjuvant Herclon™ therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. *Metastatic Gastric Cancer (MGC):* Herclon™ in combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2-positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. **Type of Dosage Form:** Powder for concentrate for solution for infusion **Dosage and Administration:** HER2 testing is mandatory prior to initiation of Herclon™ therapy. Substitution by any other biological medicinal product requires the consent of the prescribing physician. The benefit-risk of alternating or switching between Herclon™ and products that are biosimilar but not deemed interchangeable needs to be carefully considered when the safety and efficacy of alternating or switching has not been established. For intravenous (IV) infusion only. Do not administer as an intravenous push or bolus. *Weekly Schedule:* Loading Dose: 4 mg/kg body weight administered over 90 minutes; Subsequent Doses: 2 mg/kg body weight over 30 minutes (if prior dose is well tolerated). *Alternative 3-weekly Schedule:* Initial loading dose of 6 mg/kg body weight, followed by 6 mg/kg body weight 3 weeks later and then 6 mg/kg repeated at 3-weekly intervals administered as infusions over approximately 90 minutes. For EBC, administer Herclon™ for 1 year or until disease recurrence or unmanageable toxicity, whichever occurs first. Extending treatment in EBC beyond one year is not recommended. For MBC and MGC, administer Herclon™ until progression of disease or unmanageable toxicity. *Special Dosage Instructions: Geriatric use:* In clinical trials, patients ≥ 65 yea r s of a ge did not receive reduced doses of Trastuzumab for Injection. *Paediatric use:* The safety and efficacy of Trastuzumab for Injection in pediatric patients < 18 years of age have not been established. **Contraindications:** Herclon™ is contraindicated in patients with known hypersensitivity to trastuzumab or to any of its excipients. **WARNING: Preparation shall be supplied against the prescription of a Cancer Specialist Warnings and Precautions:** *Infusion related reactions (IRRs):* IRRs are known to occur with the administration of Trastuzumab injection. Patients who are experiencing dyspnoea at rest due to complications of advanced malignancy or co-morbidities may be at increased risk of a fatal infusion reaction. Therefore, these patients should not be treated with Herclon™. *Pulmonary reactions:* Severe pulmonary events have been reported with the use of Trastuzumab Injection IV in the post-marketing setting. Patients with dyspnoea at rest due to complications of advanced malignancy and co-morbidities may be at increased risk of pulmonary events. Therefore, these patients should not be treated with Herclon™. *Cardiac dysfunction:* Patients treated with Trastuzumab Injection are at increased risk of developing congestive heart failure (CHF) (New York Heart Association [NYHA] Class II-IV) or asymptomatic cardiac dysfunction. These events have been observed in patients receiving Trastuzumab Injection therapy alone or in combination with taxane following anthracycline (doxorubicin or epirubicin)-containing chemotherapy caution should be exercised in treating patients with increased cardiac risk, e.g. hypertension, documented coronary artery disease, CHF, diastolic dysfunction, older age. *Metastatic breast cancer (MBC):* Trastuzumab Injection and anthracyclines should not be given concurrently in the metastatic breast cancer setting. *Early breast cancer (EBC):* For patients with EBC, cardiac assessments, as performed at baseline, should be repeated every 3 months during treatment and every 6 months following discontinuation of treatment until 24 months from the last administration of Herclon™. *Adjuvant treatment:* Herclon™ and anthracyclines should not be given concurrently in the adjuvant treatment setting. Neoadjuvant-adjuvant treatment: In patients with EBC eligible for neoadjuvant-adjuvant treatment, Herclon™ concurrently with anthracyclines should be used with caution and only in chemotherapy-naive patients. When administering Herclon™ to a patient with known hypersensitivity to benzyl alcohol, Herclon™ should be reconstituted with water for injection, and only one dose per Herclon™ vial should be used. **Undesirable Effects:** Nasopharyngitis, Influenza; Anaemia, thrombocytopenia, leukopenia, neutropenia; weight decreased, weight increased, decreased appetite; Insomnia; Dizziness, headache, paraesthesia, hypoesthesia, dysgeusia; lacrimation increased, Conjunctivitis; Ejection fraction decreased; Lymphoedema, hot flush; Dyspnea, Epistaxis, Oropharyngeal pain, Cough, Rhinorrhea; Diarrhoea, vomiting, nausea, abdominal pain, dyspepsia, constipation, stomatitis; Erythema, rash, alopecia, nail disorder; *Musculoskeletal and connective tissue disorder:* Arthralgia, myalgia; *General disorders and administration site conditions:* Asthenia, chest pain, Chills, fatigue, influenza like illness, infusion/administration related reaction, pain, pyrexia, peripheral oedema, mucosal inflammation; Nail toxicity. The following adverse drug reactions have been identified from postmarketing experience with Herclon™: Hypoprothrombinaemia Immune thrombocytopenia, antiphylactoid reactions, tumor lysis syndrome, renal failure. **Interactions with other medicinal products and other forms of interaction:** There have been no formal drug interaction studies performed with Herclon™ in humans. Clinically significant interactions between Herclon™ and the concomitant medications used in clinical trials have not been observed. Clinical studies suggested that capecitabine showed higher concentrations and a longer half-life when combined with trastuzumab. **WARNING: Preparation shall be supplied against the prescription of a Cancer Specialist** *Use in special population: Geriatric use.* Data suggest that the disposition of Herclon™ Injection is not altered based on age *Paediatric use:* The safety and efficacy of Herclon™ in paediatric patients < 18 years of age have not been established. Females and Males of Reproductive Potential; *Fertility:* It is not known whether Herclon™ can affect reproductive capacity. *Contraception:* Women of childbearing potential should be advised to use effective contraception during treatment with Herclon™ IV or Herclon™ SC formulation and for 7 months after treatment has concluded *Renal Impairment:* In a population pharmacokinetic analysis, renal impairment was shown not to affect trastuzumab disposition. *Hepatic Impairment:* No data to report. *Pregnancy and Lactation:* Herclon™ should be avoided during pregnancy unless the potential benefit for the mother outweighs the potential risk to the fetus. Women of childbearing potential should be advised to use effective contraception during treatment with Herclon™ and for 7 months after treatment has concluded. Women who become pregnant should be advised of the possibility of harm to the foetus. It is not known whether trastuzumab is secreted in human milk. As human IgG is secreted into human milk, and the potential for harm to the infant is unknown, breast-feeding should be avoided during Herclon™ therapy. **Overdose:** There is no experience with overdose in human clinical trials. Single doses higher than 10 mg/kg have not been tested. **Storage:** Vials: Store vials at 2°C–8°C. This medicine should not be used after the expiry date (Expiry Date) shown on the pack. Shelf life of Reconstituted Solution: *440mg:-* Reconstituted solutions made with bacteriostatic water for injection are stable for 28 days when stored refrigerated at 2°C-8°C. When administering Herclon™ to a patient with a known hypersensitivity to benzyl alcohol, it should be reconstituted with water for injection. In case Herclon™ is reconstituted with water for injection, only one dose per Herclon™ vial should be used. The reconstituted solution should be used immediately. Any unused portion must be discarded. *150mg:-* The reconstituted product is physically and chemically stable for 48 hours at 2°C - 8°C after dissolving with water for injections. Do not freeze the reconstituted solution. The infusion solution (0.9% sodium chloride infusion solution) containing the reconstituted product is physically and chemically stable up to 7 days at 2°C - 8°C and 24 hours at room temperature (≤30°C). From a microbiological point of view, the Herclon™ infusion solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use is the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions. *Shelf Life:* 48 months when stored under the recommended storage conditions **WARNING: Preparation shall be supplied against the prescription of a Cancer Specialist Packs:** Currently 440mg strength of Herclon™ is marketed in India. Packing for 440 mg vial: 1 pack containing 1 vial with 440 mg Trastuzumab + 1 vial with 20 ml bacteriostatic water for injection containing 1.1% benzyl alcohol. Please read the full prescribing information before usage. Details of permission or license number with date: 12-52/2004-DC dated 11 October 2002 Date of Revision: Current at December 2020, Version 11.1

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**NOW APPROVED**

**for 18 cycles in patients with HER+eBC at high risk of recurrence[1]**

**Updated descriptive analysis:** IDFS in the node-positive subgroup

MORE PRONOUNCED treatment benefit with PERJETA–Herceptin at the updated descriptive analysis in the node-positive subgroup

PERJETA–Herceptin showed a benefit of 28% risk reduction and Δ 4.5% IDFS between treatment arms (compared with 23% and Δ 1.8% at the primary analysis) after 6 years of follow up

PERJETA® pertuzumab

Herceptin® trastuzumab

**DUAL HER2 BLOCKADE. PROVEN SYNERGY.**


Reference:
1. Gianni L, Pienkowski T, Im YH, et al. Efficacy and safety of neo-adjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): A randomised multicentre open-label, Phase II trial. Lancet oncology 2012; 13:25-32.


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For women with HER2+ eBC and residual invasive disease after neoadjuvant treatment,

# A TRANSFORMATIONAL **BREAKTHROUGH IN eBC**

**NEW INDICATION**

# Kadcyla®

ado-trastuzumab emtansine

*20 mg/mL INJECTION FOR INTRAVENOUS USE*

**TRANSFORM THE MOMENT**

APPROVED For use in Indian Patients APPROVED

## THERAPEUTIC INDICATION

KADCYLA, as a single agent, is indicated for the adjuvant treatment of patients with HER2+ eBC who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. eBC: early breast cancer; HER2+: human epidermal growth factor receptor 2- positive.[1]

Reference: 1. Indian prescribing information - Kadcyla

**Warning**: To be sold by retail on the prescription of an "Oncologist" only

ABRIDGED PRESCRIBING INFORMATION

(Kadcyla®) SUMMARY OF PRESCRIBING INFORMATION

Generic Name: Trastuzumab Emtansine for injection Brand name: Kadcyla®

**Indications:** *Metastatic Breast Cancer (MBC):* Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane.

*Early Breast Cancer (EBC):* Kadcyla, as a single agent, is indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual disease, in the breast and/or lymph nodes, after pre-operative systemic treatment that included HER2 targeted therapy. Type of Dosage form: Sterile powder for concentrate for infusion solution. Kadcyla is supplied as a single-use vial containing powder for concentrate for infusion solution, of an active ingredient (Trastuzumab emtansine) concentration of 20 mg/mL.

**Dosage and administration:** Patients treated with Kadcyla should have HER2 positive tumor status, defined as a score of 3+ by immunohistochemistry (IHC) or a ratio of ≥ 2.0 by in situ hybridization (ISH) or by fluorescence in situ hybridization (FISH) assessed by a validated test. Substitution by any other biological medicinal product requires the consent of the prescribing physician. The safety and efficacy of alternating or switching between Kadcyla and products that are biosimilar but not deemed interchangeable has not been established. Therefore, the benefit-risk of alternating or switching needs to be carefully considered. Kadcyla must be reconstituted and diluted by a healthcare professional and administered as an intravenous infusion. Do not administer as an intravenous push or bolus. Schedule: The recommended dose of Kadcyla is 3.6 mg/kg given as an intravenous infusion every 3 weeks (21-day cycles). Administer the initial dose as a 90 minute intravenous infusion. Patients should be observed during the infusion and for at least 90 minutes following the initial dose for fever, chills, or other infusion related reactions. The infusion site should be closely monitored for possible subcutaneous infiltration during drug administration. If prior infusions were well tolerated, subsequent doses of Kadcyla may be administered as 30 minute infusions and patients should be observed during the infusions and for at least 30 minutes after infusion. The infusion rate of Kadcyla should be slowed or interrupted if the patient develops infusion-related symptoms. Discontinue Kadcyla for life-threatening infusion reactions. Duration of treatment: Patients with EBC should receive treatment for a total of 14 cycles unless there is disease recurrence or unmanageable toxicity. Patients with MBC should receive treatment until disease progression or unmanageable toxicity. Delayed or Missed dose: If a planned dose of Kadcyla is missed, it should be administered as soon as possible; do not wait until the next planned cycle. The schedule of administration should be adjusted to maintain a 3-week interval between doses. The infusion may be administered at the rate the patient tolerated the most recent infusion. Contraindications: Kadcyla is contraindicated in patients with a known hypersensitivity to Kadcyla or any of the excipients. Warnings and Precautions: *Pulmonary Toxicity:* Cases of interstitial lung disease (ILD), including pneumonitis, were reported, some leading to acute respiratory distress syndrome or a fatal outcome, have been reported in clinical trials with Kadcyla. It is recommended that treatment with Kadcyla be permanently discontinued in patients who are diagnosed with ILD or pneumonitis except for radiation pneumonitis in the adjuvant setting, where Kadcyla should be permanently discontinued for ≥ Grade 3 or for Grade 2 not responding to standard treatment. Patients with dyspnea at rest due to complications of advanced malignancy and comorbidities may be at greater risk of pulmonary events. *Hepatotoxicity:* Hepatotoxicity, predominantly in the form of asymptomatic increases in the concentrations of serum transaminases (Grade 1–4 transaminitis), has been observed while on treatment with Kadcyla in clinical trials. Serious hepatic events, including drug induced liver injury, hepatitis, and hepatic failure have been observed in patients treated with Kadcyla in clinical trials. Upon diagnosis of MRH, Kadcyla treatment must be permanently discontinued. Liver function should be monitored prior to initiation of treatment and each Kadcyla dose. Kadcyla treatment in patients with serum transaminases >3x ULN and concomitant total bilirubin >2x ULN should be permanently discontinued. Dose reductions or discontinuation for increased serum transaminases and total bilirubin are specified in the full prescribing information. Kadcyla has not been studied in patients with serum transaminases >2.5x ULN or total bilirubin >1.5x ULN prior to initiation of treatment. Kadcyla treatment in patients with serum transaminases >3x ULN and concomitant total bilirubin >2x ULN should be permanently discontinued. *Left Ventricular Dysfunction:* Patients treated with Kadcyla are at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) ≥ 40% has been observed in patients treated with Kadcyla, and therefore symptomatic congestive heart failure (CHF) is a potential risk. The decision to administer Kadcyla in patients with mBC with low LVEF must be made only after careful benefit risk assessment and cardiac function should be closely monitored in these patients. Specific guidelines regarding dose modifications and discontinuation are provided in full prescribing information. *Infusion-Related Reactions:* Treatment with Kadcyla has not been studied in patients who had trastuzumab permanently discontinued due to infusion-related reactions (IRR); treatment with Kadcyla is not recommended for these patients. Kadcyla treatment should be interrupted in patients with severe IRR. Kadcyla treatment should be permanently discontinued in the event of a life threatening infusion-related reaction. *Hypersensitivity Reactions:* Patients should be observed closely for hypersensitivity reactions, especially during the first infusion. *Hemorrhage:* Cases of hemorrhagic events, including cerebral nervous system, respiratory, and gastrointestinal hemorrhage, have been reported with Kadcyla. Some of these bleeding events resulted in fatal outcomes. *Thrombocytopenia:* Thrombocytopenia, or decreased platelet counts, was reported in patients in clinical trials of Kadcyla. In clinical trials, the incidence and severity of thrombocytopenia were higher in Asian patients. It is recommended that platelet counts are monitored prior to each Kadcyla dose. *Neurotoxicity:* Peripheral neuropathy, mainly Grade 1 and predominantly sensory, has been reported in clinical trials of Kadcyla. Patients should be clinically monitored on an ongoing basis for signs/symptoms of neurotoxicity. *Extravasation:* In Kadcyla clinical studies, reactions secondary to extravasation have been observed. These reactions have been observed more frequently within 24 hours of infusion. Use in Special Populations: *Geriatric Use:* No dose adjustment of Kadcyla is required in patients aged ≥ 65 years. There are insufficient data to establish the safety and efficacy of Kadcyla in patients 75 years of age or older. *Pediatric Use:* The safety and efficacy of Kadcyla in children and adolescents (< 18 years) have not been established. Renal impairment: No adjustment to the starting dose of Kadcyla is needed in patients with mild or moderate renal impairment. Hepatic Impairment: No adjustment to the starting dose is required for patients with mild or moderate hepatic impairment. Kadcyla has not been studied in patients with severe hepatic impairment. Treatment of patients with hepatic impairment should be undertaken with caution due to known hepatotoxicity observed with Kadcyla. *Females and Males of Reproductive Potential: Contraception:* Women of child-bearing potential and female partners of male patients or child-bearing potential should use effective contraception while receiving Kadcyla and for at least 7 months following the last dose of Kadcyla. *Pregnancy:* No clinical studies of Kadcyla in pregnant women have been performed. No reproductive and developmental toxicology studies have been conducted with Kadcyla. Trastuzumab, a component of Kadcyla, can cause fetal harm or death when administered to a pregnant woman. Administration of Kadcyla to pregnant women is not recommended. Women who become pregnant must contact their doctor and should be advised of the possibility of harm to the fetus. *Lactation and Delivery:* The safe use of Kadcyla during labor and delivery has not been established. *Lactation:* It is not known whether Kadcyla is excreted in human breast milk. Since many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Kadcyla, women should discontinue nursing prior to initiating treatment with Kadcyla. Women may begin nursing 7 months following the last dose of Kadcyla. Undesirable Effects: TRA is not the complete list. From Clinical trials, the very commonly reported adverse events were fatigue, pyrexia, musculoskeletal pain, arthralgia, myalgia, headache, neuropathy peripheral, insomnia, epistaxis, cough, dyspnoea, rash, subconjunctival haemorrhage, thrombocytopenia, anemia, nausea, constipation, stomatitis, vomiting, dry mouth, diarrhea, abdominal pain, UTI, transaminases increased, asthenia, chills and hypokalemia. No new data are available on undesirable effects from the Post marketing experience, interactions with other medicinal products and other forms of interaction: no formal drug-drug interaction studies with Kadcyla in humans have been conducted. In vitro metabolism studies in human liver microsomes suggest that DM1, a component of trastuzumab emtansine, is metabolized mainly by CYP3A4 and, to a lesser extent, by CYP3A5. DM1 does not induce or inhibit P450-mediated metabolism in vitro. Caution should be taken when Kadcyla is co-administered with potent CYP3A inhibitors. Overdose: There is no known antidote for trastuzumab emtansine overdose. In case of overdose, the patient should be closely monitored. Storage condition: Vials - Store vials at 2–8°C until time of reconstitution. The medicine should not be used after the expiry date (Expiry Date) shown on the pack. Shelf life of product is 36 months when stored under the recommended storage conditions. Shelf-life of the reconstituted solution - Product vials reconstituted with sterile water for injection should be used immediately following reconstitution. If not used immediately, the reconstituted vials can be stored for up to 24 hours at 2–8°C, and must be discarded thereafter. Do not freeze the reconstituted solution. Shelf-life of the solution for infusion containing the reconstituted product - The reconstituted Kadcyla solution diluted to polyvinyl chloride (PVC) or latex-free PVC-free polyolefin bags containing 0.9% Sodium Chloride injection, or 0.45% Sodium Chloride injection, may be stored at 2–8°C for up to 24 hours prior to use. Particulates may be observed on storage if diluted to 0.9% Sodium Chloride injection, therefore, a 0.2 or 0.22 micron in-line polyethersulfone (PES) filter is required for administration. Do not freeze the solution for infusion containing the reconstituted product. Kadcyla should not be mixed or diluted with other drugs. Packs: Each pack contains a single-use vial of 100mg or 160mg of trastuzumab emtansine. 100 mg single use vial: 1 pack containing 15 mL glass vial that contains 100 mg of trastuzumab emtansine. 160 mg single use vial: 1 pack containing 20 mL glass vial that contains 160 mg of trastuzumab emtansine. Please read full prescribing information before usage. Details of Permission or Licence Number with date: Ref/-258/2014 dated 19 December 2014. Date of Revision: Current as December 2022. version 0.1.

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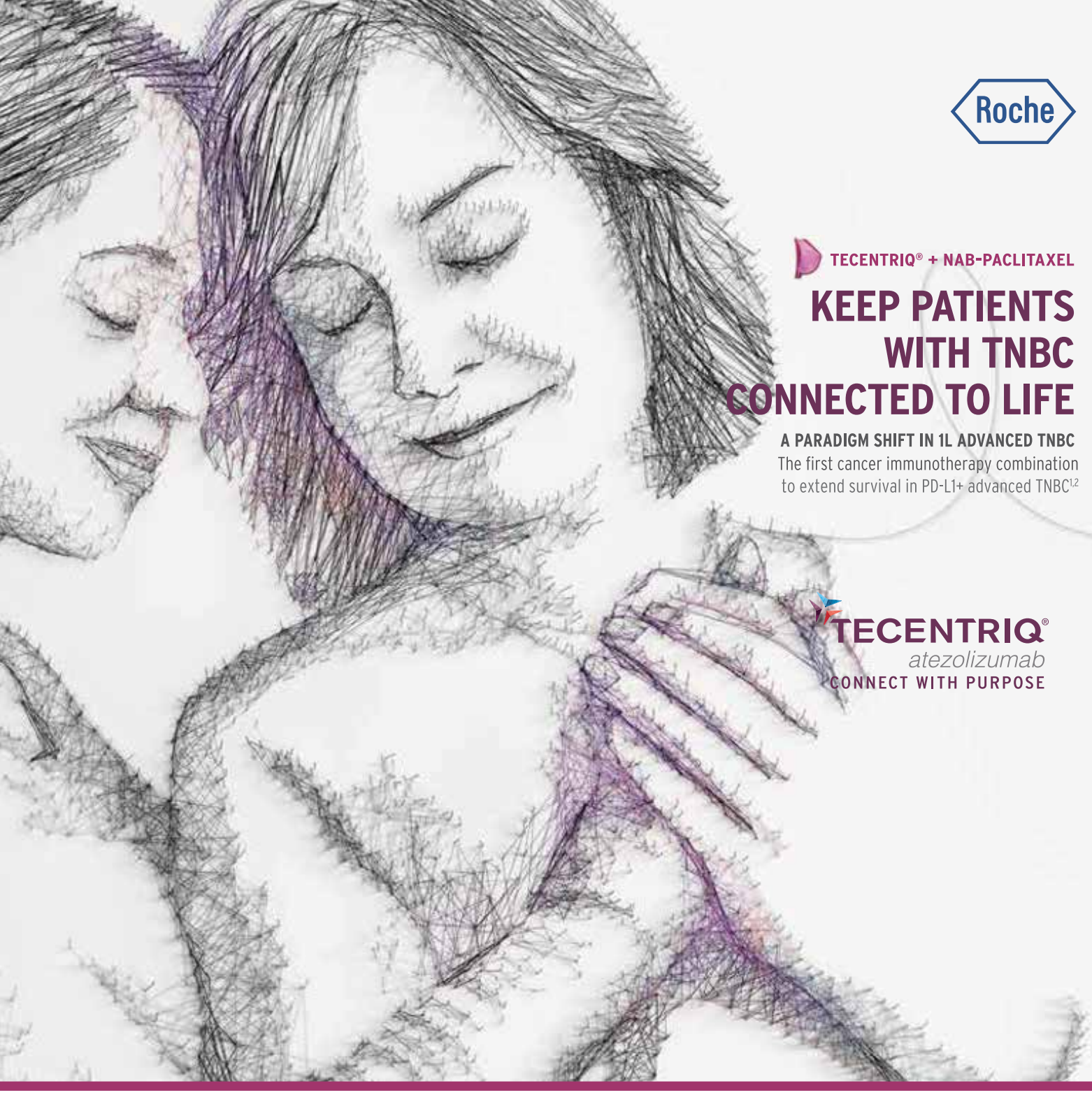

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The first cancer immunotherapy combination to extend survival in PD-L1+ advanced TNBC[1,2]

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## Indication

Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease.

1L=first line; PD-L1=programmed death-ligand 1.


Reference:

1. Indian Prescribing information of Tecentriq
2. Schmid P, Adams S, Rugo H S, et al. IM Passion 130: Updated overall survival (OS) from a global, randomized, double blind placebo controlled, Phase III study of Atezolizumab (Atezo) + nab-paclitaxel (nP) in previously treated locally advanced or metastatic triple negative breast cancer (mTNBC). Presented at 2019 American society of clinical oncology (ASCO) annual meeting; May 31-June 4, 2019, Chicago, Abstract 1003


WARNING: To be sold by retail on the prescription of a "Registered Oncologist Only"
ABRIDGED PRESCRIBING INFORMATION
(Tecentriq ®) SUMMARY OF PRESCRIBING INFORMATION:
Generic Name: Atezolizumab Injection Brand Name: Tecentriq® Composition: Active ingredient: Atezolizumab.
Tecentriq is supplied as a single-use vial containing preservative-free, colorless to slightly yellow solution, at an active ingredient concentration of 60 mg/mL as follows: • 14 mL vial containing a total of 840 mg atezolizumab • 20 mL vial containing a total of 1200 mg atezolizumab Indications: Tecentriq® is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma after prior chemotherapy or who are considered cisplatin ineligible. Non-small cell lung cancer Tecentriq is also indicated for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC) after prior chemotherapy. Tecentriq in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies. Small cell lung cancer Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). Triple-negative breast cancer Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease. Type of dosage form: Tecentriq® is available in single use vials as Concentrate for solution for infusion. Dosage and Administration: Tecentriq must be administered as an intravenous infusion under the supervision of a qualified healthcare professional. Do not administer as an IV push or bolus. WARNING: To be sold by retail on the prescription of a "Registered Oncologist Only" The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes. The recommended dose of Tecentriq in monotherapy or combination therapy: • 840 mg administered by IV infusion every 2 weeks, or • 1200 mg administered by IV infusion every 3 weeks Tecentriq monotherapy 2L NSCLC, 2L UC & 1L UC in Cisplatin ineligible patients Tecentriq combination therapy 1L non-squamous NSCLC: Tecentriq in combination with bevacizumab, paclitaxel, and carboplatin. During the induction phase, Tecentriq is administered according to its dosing schedules by intravenous (IV) infusion and bevacizumab, paclitaxel and carboplatin are administered every 3 weeks for four or six cycles. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion and bevacizumab is administered every 3 weeks. 1L ES-SCLC: Tecentriq in combination with carboplatin and etoposide During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion and carboplatin and etoposide are administered by IV infusion every three weeks for four cycles. Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion. 1L TNBC: Tecentriq in combination with nab-paclitaxel The recommended dose of Tecentriq is 840 mg administered by IV infusion, followed by 100 mg/m2 nab-paclitaxel. For each 28-day cycle Tecentriq is administered on days 1 and 15, and nab-paclitaxel is administered on days 1, 8 and 15. Duration of Treatment: Patients are treated with Tecentriq until disease progression or unacceptable toxicity in UC, NSCLC & ES-SCLC and patients are treated until disease progression or unacceptable toxicity in 1L TNBC. Contraindications: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. Warnings and Precautions: Immune-mediated pneumonitis: Cases of pneumonitis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 pneumonitis. WARNING: To be sold by retail on the prescription of a "Registered Oncologist Only" Immune-mediated hepatitis: Cases of hepatitis, some leading to fatal outcomes, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or Grade 4 events. Immune-mediated colitis: Cases of diarrhea or colitis have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4 diarrhea or colitis. Immune-mediated endocrinopathies: Hypothyroidism, hyperthyroidism, adrenal insufficiency and type 1 diabetes mellitus, including diabetic ketoacidosis, have been observed in clinical trials with Tecentriq. For Grade 4 Hypophysitis, treatment with Tecentriq should be permanently discontinued. Immune-mediated meningoencephalitis: Meningoencephalitis has been observed in clinical trials with Tecentriq. Permanently discontinue for all grades of meningoencephalitis. Immune-mediated neuropathies: Myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome, which may be life threatening, were observed in patients receiving Tecentriq Permanently discontinue Tecentriq for all grades of immune mediated neuropathies. Immune-mediated pancreatitis: Pancreatitis, including increases in serum amylase and lipase levels, has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4, or any grade of recurrent pancreatitis. Immune-mediated myocarditis: Myocarditis has been observed in clinical trials with Tecentriq Tecentriq should permanently discontinued for Grade 3 or 4 myocarditis. Immune-mediated myositis: Cases of myositis, including fatal cases, have been observed in cli nical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 recurrent myositis or Grade 4 events. Immune-mediated nephritis: Nephritis has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 nephritis. Infusion related reactions: Infusion related reactions (IRRs) have been observed in clinical trials with Tecentriq. Tecentriq should be permanently discontinued in patients with Grade 3 or 4 infusion related reactions. Immune-mediated severe cutaneous adverse reactions: Immune-mediated severe cutaneous adverse reactions (SCARs), including cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients receiving Tecentriq. Patients should be monitored for suspected severe skin reactions and other causes should be excluded. Tecentriq should be permanently discontinued for Grade 4 skin reactions, and corticosteroids should be administered. For confirmed SJS or TEN, Tecentriq should be permanently discontinued. Special populations: Patients with autoimmune disease were excluded from clinical trials with Tecentriq. In the absence of data, Tecentriq should be used with caution in patients with autoimmune disease, after assessment of the potential risk-benefit. Embryofetal toxicity: Based on the mechanism of action, the use of Tecentriq may cause fetal harm. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related rejection of the developing fetus resulting in fetal death. Pregnant women should be advised of the potential risk to the fetus. Women of childbearing potential should be advised to use highly effective contraception during treatment with Tecentriq and for 5 months after the last dose. Use in Special population: Fertility: Based on animal studies, Tecentriq may impair fertility in females of reproductive potential while receiving treatment. Contraception: Female patients of childbearing potential should use highly effective contraception and take active measures to avoid pregnancy while undergoing Tecentriq treatment and for at least 5 months after the last dose. WARNING: To be sold by retail on the prescription of a "Registered Oncologist Only" Pregnancy: There are no clinical studies of Tecentriq in pregnant women. Tecentriq is not recommended during pregnancy unless the potential benefit for the mother outweighs the potential risk to the fetus. Labor and Delivery: The use of Tecentriq during labor and delivery has not been established. Lactation: It is not known whether Tecentriq is excreted in human breast milk. No studies have been conducted to assess the impact of Tecentriq on milk production or its presence in breast milk. As the potential for harm to the nursing infant is unknown, a decision must be made to either discontinue breast-feeding or discontinue Tecentriq therapy. Pediatric use: Tecentriq is not approved for use in patients under the age of 18 years. The safety and efficacy of Tecentriq in this population has not been established. Tecentriq did not demonstrate clinical benefit in pediatric patients in a clinical trial. Geriatric use: No overall differences in safety or efficacy were observed between patients ≥ 65 years of age and younger patients. Undesirable Effects: This is not the complete list. The very commonly reported Adverse Events (AEs) with Tecentriq in monotherapy includes fatigue, decreased appetite, cough, nausea, dyspnea, , diarrhea, pyrexia, vomiting, arthralgia, Musculoskeletal pain, back pain, urinary tract infection, asthenia, pruritus, rash, headache and in case of combination therapy it includes anemia, neutropenia, thrombocytopenia, leukopenia, hypothyroidism, constipation, peripheral oedema, lung infection, peripheral neuropathy, nasopharyngitis, alopecia, hypertension. No new adverse drug reactions have been identified from post marketing experience. Interactions with other medicinal products and other forms of interaction: No formal pharmacokinetic drug-drug interaction studies have been conducted with atezolizumab. Since atezolizumab is cleared from the circulation through catabolism, no metabolic drug-drug interactions are expected. Overdose: There is no information on overdose with Tecentriq. Storage: Vials: - Store in a refrigerator at 2°C - 8°C. Keep vial in the outer carton in order to protect from light. DO NOT FREEZE. DO NOT SHAKE. This medicine should not be used after the Expiry Date shown on the pack. The diluted solution for infusion should be used immediately. If the solution is not used immediately, it can be stored for up to 30 days at 2°C-8°C, or 24 hours at ambient temperature (≤ 25°C) if prepared under aseptic conditions. This medicinal product must not be mixed with other medicinal products. Shelf-life: 3 Years for Atezolizumab Injection 1200mg/20ml and 2 Years for Atezolizumab Injection 840mg/14ml Please read full prescribing information before usage. Details of Permission or License Number with date: IMP-063/2017 dated 31 March 2017 [1200mg/20ml] and dated 27 Sept 2019 [840mg/14ml] Date of Revision:Current at December 2020, Version 16.0

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**According to the NCCN Guidelines®, PALBACE® + Letrozole is one of the Category 1 recommendations for first-line treatment of patients with ER+/HER2- advanced breast cancer.[5]**

PALBACE® has also demonstrated a consistent and manageable safety profile[4,6,7], without exerting clinically relevant effects on the QTc interval[8]

*For patients who experience a maximum of Grade 1 or 2 neutropenia in the first 6 cycles, monitor complete blood counts for subsequent cycles every 3 months, prior to the beginning of a cycle and as clinically indicated.


**References**

**1.** Lu J. Palbociclib: a first-in-class CDK4/CDK6 inhibitor for the treatment of hormone-receptor positive advanced breast cancer. J HematolOncol. 2015 Aug 13;8:98. **2.** Palbociclib (IBRANCE Capsules). Approved drugs, drug approvals and databases. U.S. Food & Drug Administration [updated 2016 Feb 22; cited 2019 Mar 08].Available from: https://www.fda.gov/drugs/informationdrugs/approveddrugs/ucm487080.htm **3.** Palbace(Palbociclib) Local Prescribing Document, Pfizer Products India Private Limited. Version 8.0, LPDPAB112018. **4.** Rugo HS, Finn RS, Diéras V, et al. Palbociclib plus letrozole as first-line therapy in estrogen receptor–positive/human epidermal growth factor receptor 2–negative advanced breat cancer with extended follow-up. Breast cancer Res.Treat. 2019 Jan 10.[Epubahead of print] **5.** Breast cancer. Version 1.2019. NCNN clinical practice guidelines in oncology [updated 2019 Feb 08; cited 2019 Jun 24]. Available from: https://www.nccn.org/professionals/physician_gls/default.aspx#breast **6.** Finn RS, et al. The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): a randomised phase 2 study. Lancet Oncol 2015;16:25-35 **7.** Turner NC, Slamon DJ, Ro J, et al. Overall Survival with Palbociclib and Fulvestrant in Advanced Breast Cancer. N England J Med. 2018 Nov 15;379 (20):1926-1936. **8.** Durairaj C, Ruiz-Garcia A, Gauthier ER, et al. Palbociclib has no clinically relevant effect on the QTc interval in patients with advanced breast cancer. Anticancer Drugs. 2018 Mar;29(3):271-280


CDK - Cyclin Dependent Kinase, ER - Estrogen Receptor, HER - Human Epidermal growth factor Receptor, mBC - metastatic breast cancer, mPFS - median progression free survival HR-Hazard Ratio, CI - Confidence Interval, NCCN - National Comprehensive Cancer Network, QTc = QT interval corrected for heart rate

**SUMMARY OF PRESCRIBING INFORMATION FOR PALBOCICLIB**
**(Based on LPD version 8.0, SPI_LPDPAB112018)**

**Composition:** Each capsule contains 125 mg, 100 mg or 75 mg of Palbociclib. **Indications:** 1. Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. 2. Palbociclib is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy. **Contraindications:** None. **Adverse reactions:** The most common adverse reactions (≥10%) of any Grade reported in patients in the Palbociclib plus letrozole arm by descending frequency were neutropenia, infections, leukopenia, fatigue, nausea, alopecia, stomatitis, diarrhea, anemia, rash, asthenia, thrombocytopenia, vomiting, decreased appetite, dry skin, pyrexia and dysgeusia. The most frequently reported Grade ≥3 adverse reactions (≥5%) in patients receiving Palbociclib plus letrozole were neutropenia, leukopenia, infections and anemia. The most common adverse reactions (≥10%) of any grade reported in patients in the Palbociclib plus fulvestrant arm by descending frequency were neutropenia, leukopenia, infections, fatigue, nausea, anemia, stomatitis, diarrhea, thrombocytopenia, vomiting, alopecia, rash, decreased appetite, and pyrexia. The most frequently reported Grade ≥3adverse reactions (≥5%) in patients receiving Palbociclib plus fulvestrant in descending frequency were neutropenia and leukopenia. **Warnings and Precautions:** Neutropenia was the most frequently reported adverse reaction in Study1 with an incidence of 80% and Study 2 with an incidence of 83%. A Grade ≥3 decrease in neutrophil counts was reported in 66% of patients receiving Palbociclib plus letrozole in Study 1 and 66% of patients receiving Palbociclib plus fulvestrant in Study 2. Febrile neutropenia has been reported in 1.8% of patients exposed to Palbociclib across Studies 1 and 2. One death due to neutropenic sepsis was observed in Study 2. Physicians should inform patients to promptly report any episodes of fever. Monitor complete blood count prior to starting Palbociclib therapy and at the beginning of each cycle, as well as on Day 15 of the first 2 cycles, and as clinically indicated. Dose interruption, dose reduction or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia. Palbociclib can cause fetal harm. Advise females of reproductive potential to use effective contraception during therapy with Palbociclib and for at least three weeks after the last dose. The safety and efficacy of Palbociclib in children and adolescents ≥18 years of age have not been studied. Recommended starting dose of Palbociclib is 75 mg once daily Patients with severe hepatic impairment. **Dosage**: The recommended dose of Palbociclib is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days. Palbociclib should be taken with food, in combination with letrozole 2.5 mg once daily given continuously throughout the 28-day cycle or with fulvestrant 500 mg administered intramuscularly on Days 1, 15, 29, and once monthly thereafter. Dose modification of Palbociclib is recommended from 125 mg/day to 100 mg/day to 75 mg/day based on individual safety and tolerability. If further dose reduction below 75 mg/day is required, discontinuation of the treatment is recommended. Refer to full prescribing information for details.

Full prescribing information available on request

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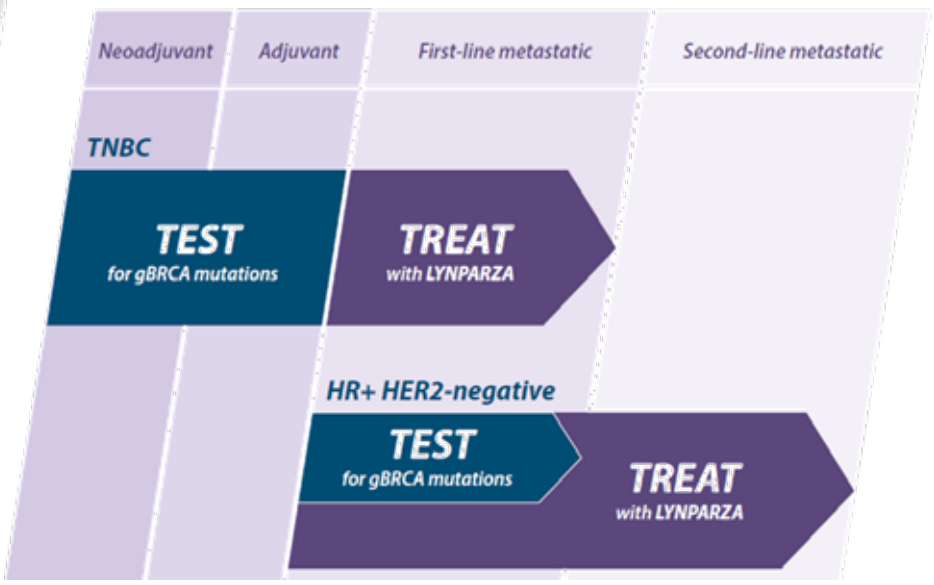
# Choose LYNPARZA: The first PARPi for gBRCAm patients with HER2-negative locally advanced or metastatic breast cancer[1]

Lynparza® olaparib tablets 150 mg




**Test your HER2-ve patients for gBRCA mutations to identify those eligible to benefit from LYNPARZA**

**Significantly improved median PFS vs. chemotherapy[2]**

| LYNPARZA (n=205) | Chemotherapy*(n=97) |
|---|---|
| 7.0 months | 4.2 months |

HR=0.58 [95% CI: 0.43–0.80]; P<0.001

**Doubled ORR[2]**

| LYNPARZA (n=205) | Chemotherapy*(n=97) |
|---|---|
| 59.9% | 28.8% |
| 95% CI: 52.0–67.4 | 95% CI: 18.3–41.3 |

**Consistent safety profile**

**95%**

of patients stayed on LYNPARZA without discontinuing due to AEs

*Treatment of physician's choice (eribulin, capecitabine or vinorelbine). AE=adverse event; CI=confidence interval; gBRCA= germline BRCA; gBRCAm=germline BRCA-mutated; HR=hazard ratio; ORR=objective response rate; PARPi=poly (ADP-ribose) polymerase inhibitor; PFS=progression-free survival. **References** Lynparza® full prescribing information Version 6, dated 25th Aug 2020 2. Robson M et al. N Engl J Med. 2017;377(6):523–533.

For the use of registered oncologist only Olaparib Tablets LYNPARZA® 100 mg and 150 mg Abbreviated Prescribing Information: QUALITATIVE AND QUANTITATIVE COMPOSITION: Each 150 mg film-coated tablet contains 150 mg of olaparib. Each 100 mg film-coated tablet contains 100 mg of olaparib. INDICATIONS: LYNPARZA is indicated in: Ovarian Cancer: i) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy ii) for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy iii) for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy iv) Lynparza in combination with bevacizumab is indicated for the maintenance treatment of adult patients with advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to first line platinum-based chemotherapy with bevacizumab. Breast Cancer: In patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment Prostate cancer: Lynparza is indicated as monotherapy for the: treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair gene mutations (germline and/or somatic) who have progressed following a prior new hormonal agent Adenocarcinoma of the pancreas: Lynparza is indicated as monotherapy for the: maintenance treatment of adult patients with germline BRCA-mutated metastatic adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy. DOSAGE & ADMINISTRATION: The recommended dose of LYNPARZA is 300 mg (two 150 mg tablets) taken twice daily, equivalent to a total daily dose of 600 mg. The 100 mg tablet is available for dose reduction. Duration of treatment: Maintenance treatment of newly diagnosed advanced ovarian cancer: can continue treatment for 2 years or until disease progression. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating physician can derive further benefit from continuous treatment, can be treated beyond 2 years. Advanced gBRCA-mutated Ovarian Cancer :Continue treatment until disease progression or unacceptable toxicity. Platinum sensitive relapsed ovarian cancer: it is recommended that treatment be continued until progression of the underlying disease Maintenance treatment of newly diagnosed advanced ovarian cancer in combination with bevacizumab patients can continue treatment for 2 years or until disease progression. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating physician can derive further benefit from continuous Lynparza treatment, can be treated beyond 2 years Metastatic HER2-negative breast cancer: it is recommended that treatment be continued until progression of the underlying disease. HRR-gene mutated metastatic castration-resistant prostate cancer: it is recommended that treatment be continued until progression of the underlying disease Maintenance following first-line treatment of metastatic adenocarcinoma of the pancreas: It is recommended that treatment be continued until progression of the underlying disease CONTRAINDICATIONS: None. WARNINGS & PRECAUTIONS: Haematological toxicity: Haematological toxicity has been reported in patients treated with LYNPARZA including generally mild or moderate anaemia, neutropenia, thrombocytopenia and lymphopenia. If a patient develops severe haematological toxicity or blood transfusion dependence, treatment with LYNPARZA should be interrupted. Myelodysplastic Syndrome/Acute Myeloid Leukaemia: The incidence of MDS/AML in patients treated in clinical trials with LYNPARZA monotherapy was <1.5% and majority of events had a fatal outcome. If MDS and/or AML are confirmed while on treatment with LYNPARZA, it is recommended that LYNPARZA should be discontinued and the patient be treated appropriately. Pneumonitis: Pneumonitis has been reported in <1.0% patients treated with LYNPARZA monotherapy in clinical studies. If pneumonitis is confirmed, LYNPARZA treatment should be discontinued and the patient treated appropriately. Embryofoetal toxicity: Based on its mechanism of action (PARP inhibition), LYNPARZA could cause foetal harm when administered to a pregnant woman. LYNPARZA should not be taken during pregnancy Breast-feeding: The excretion of olaparib in milk has not been studied in animals or in breastfeeding mothers. Interactions with other medicinal products: Co-administration of LYNPARZA with strong or moderate CYP3A inhibitors is not recommended. If a strong or moderate CYP3A inhibitor must be co-administered, the dose of LYNPARZA should be reduced. Co-administration of LYNPARZA with strong or moderate CYP3A inducers is not recommended. UNDESIRABLE EFFECTS: The most commonly reported adverse drug reactions (ADRs), reported in more than 10% of the patients and greater than placebo/ active comparator were: Anemia, Neutropenia and/or Leukopenia, Decreased apetite, Dizzyness, Headache, Cough, Dysguesia, Vomiting, Nausea and Diarrhoea, Fatigue. INTERACTIONS:Concomitant use of itraconazole as well as other strong CYP3A inhibitors is not recommended with LYNPARZA due to an increase in Cmax and AUC. CYP3A inducers could substantially diminish the clinical efficacy of LYNPARZA and concomitant use of strong inducers is not recommended. PHARMACOLOGICAL PROPERTIES:Mechanism of action Olaparib is a potent inhibitor of human poly (ADP ribose) polymerase enzymes (PARP 1, PARP 2, and PARP 3), and has been shown to inhibit the growth of selected tumour cell lines in vitro and tumour growth in vivo either as standalone treatment or in combination with established chemotherapies Pharmacokinetic properties The pharmacokinetics of olaparib at the 300 mg tablet dose is characterized by an apparent plasma clearance of ~7 L/h, an apparent volume of distribution of ~158 L and a terminal halflife of 15 hours. The in vitro plasma protein binding is approximately 82% at 10 µg/mL. CYP3A4/5 were shown to be the enzymes primarily responsible for the metabolism of olaparib. Post administration, ~86% of the dose was recovered within a 7-day collection period, ~44% via the urine and ~42% via the faeces. Majority of the material was excreted as metabolites. PHARMACEUTICAL PARTICULARS PRESENTATION & STORAGE: LYNPARZA 150 mg tablet is a green to green/grey, oval, bi-convex tablet debossed with 'OP150' on one side and plain on the reverse. LYNPARZA 100 mg tablet is a yellow to dark yellow, oval, bi-convex tablet debossed with 'OP100' on one side and plain on the reverse. This medicinal product does not require any special temperature storage conditions. SHELF LIFE: Please refer outer carton. LYNPARZA® is trademark of AstraZeneca group of companies. For Further information contact: AstraZeneca Pharma India Ltd., Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bengaluru – 560 045 www.astrazenecaindia.com. For more information, refer full prescribing information Version 6, dated 25th Aug 2020. API Version 5 Dated 25th Aug 2020.

Approval ID: IN-5975 Approval Date: 08/01/2021 Expiry: 08/01/2023

# 6th YEAR IN REVIEW BREAST CANCER

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