



PROTON
Cancer Centres

2nd Annual Breast Oncology Conference

Breast Cancer Treatments

Expanding Horizons

30th - 31st October, 2021

Time: 17:00 - 20:00

Save The Date

Program Convenors



Dr. Bhawna Sirohi
Lead Medical
Oncologist



Dr. Sapna Nangia
Senior Consultant
Radiation Oncologist



Dr. Manjula Rao
Consultant - Oncoplastic
Breast Surgeon

Click the link below to register
<https://www.riverroute.in/apccbrestmeet>

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Welcome Address

Greetings everyone, it is our pleasure to invite you all to the second annual APCC Breast Oncology Conference, that will be held virtually this year on the **30th & 31st of October, 2021 between 17:00 - 20:00 IST.**

The theme of the conference for this year is **Breast Cancer Treatments - Expanding Horizons.**

Breast Oncology is a rapidly evolving field. As we come to understand the biology of Breast Cancer a bit better with every passing day, it has led to exciting novel developments in medical, radiation and breast surgical oncology. Further enriching our treatment armamentarium with an array of new surgical techniques being described, a smorgasbord of new drugs appearing on the horizon on a regular basis and exciting new technologies and regimens coming to the fore, it is now more imperative than ever, that we look at these new developments with a critical eye and choose wisely, while tailoring treatments apt for our patients.

The objective of this conference is to dissect applications of newer concepts in breast oncology, learn novel tricks and offer tips in breast surgery, critique, debate and deliberate over emerging molecules, radical surgical approaches and latest technologies of radiation delivery to guide us in their routine clinical applications.

Do register for the meeting through the link mentioned below and spread the word amongst your students, friends, colleagues and seniors. We look forward to have you to join us in what we hope would be an exciting and enriching academic extravaganza.

Regards,

Dr. Bhawna Sirohi

Lead Medical
Oncologist

Dr. Sapna Nangia

Senior Consultant
Radiation Oncologist

Dr. Manjula Rao

Consultant - Oncoplastic
Breast Surgeon

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Chief Patron

Dr. Prathap C. Reddy

Founder & Chairman,
Apollo Hospitals Group



Patron

Ms. Preetha Reddy

Executive Vice Chairperson,
Apollo Hospitals Group

Advisors



Mr. Dinesh Madhavan

President,
Group Oncology & International,
AHCL



Mr. Harshad Reddy

Director - Operations,
Apollo Proton Cancer Centre



Dr. Rakesh Jalali

Medical Director,
Apollo Proton Cancer Centre



Mr. Harish Trivedi

Chief Executive Officer,
Apollo Proton Cancer Centre

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Guests of Honor



Prof. (Dr.) R. A. Badwe

Director,
Tata Memorial Centre,
Mumbai

Dr. R. A. Badwe has more than 25 years diverse experience as a Surgical Oncologist, and as Director, he has led Tata Memorial Centre transformation into a world renowned institution in the field of cancer care. Dr. A. Dorab Tata Scholar (1974-1978), he has been a recipient of several prestigious International and National awards, the most recent being the UICC Reach to Recovery International Medal (2003) and Sushurat Award (2007) by Mumbai Medical Foundation for outstanding contributions in Surgery and Padma Shri National Award (2013). He underwent training in Breast Cancer at Royal Marsden Hospital, London (1989-1992). His original research "On Timing of Surgery during the Menstrual Cycle for Operable Breast Cancer" has changed the Treatment Planning in England and East Coast of USA. He is on several scientific committees globally. Beside, being a reviewer to several International journals, he has many publications to his credit.



Prof. (Dr.) G. K. Rath

Director National Cancer Institute, Jhajjar
Chief Radiologist and Professor,
Head Dept of Radiation Oncology,
Dr. BRA Institute Rotary Cancer Hospital,
New Delhi

Prof. (Dr.) G K Rath has been instrumental in various developments in India in the field of oncology, oncology research, guidelines and preventive oncology. Dr. Rath has been instrumental in developing Dr. BRA Institute Rotary Cancer Hospital at the AIIMS and National Cancer Institute, Jhajjar. Dr. Rath is considered as a stalwart and father figure in the field of radiation oncology. He has various awards and publications to his credit.

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Mentor of the Program



Dr. Ramesh Sarin

Senior Consultant Surgical Oncologist &
Breast Cancer Specialist,
Indraprastha Apollo Hospitals,
Delhi

Dr. Sarin is one of the pioneers on surgical treatment for breast cancer in India. Dr. Sarin has a work experience of 40 years which includes working in UK for 6 years, where Dr. Sarin obtained FRCS degree. She was an Assistant Professor of Surgery at AIIMS from January 1975 to December 1982 and Assistant Professor of Surgery at AIIMS from January 1983 till 1986. Dr. Sarin has started the first ever Breast Cancer Clinic at AIIMS. She did her fellowship in Surgical Oncology at Memorial Sloane Kettering Cancer Centre, New York (1979-1980). She was a head of Surgical Oncology Ministry of Health at Mafrao Hospital, Abu Dhabi UAE (helped in starting a cancer centre in UAE). Dr. Sarin is the Founder member and initiated Indian Society of Oncology (ISO). Dr. Sarin is passionate about breast cancer awareness at large and also chairs an NGO called "Forum for Breast Protection".

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Introducing International Speakers



Mr. Venkat Ramakrishnan

Consultant Plastic Surgeon,
Head of the Breast Reconstruction Service
St. Andrews Centre for Plastic Surgery,
Chelmsford, UK

Mr. Venkat Ramakrishnan is a highly experienced Plastic Surgeon with an International reputation for his work in Microsurgical Breast Reconstruction. Mr. Ramakrishnan's specialist areas of interest include reconstructive and cosmetic breast surgery, liposculpting and body lifts, cosmetic facial surgery. His research currently focuses on outcomes after reconstructive breast surgery and he regularly presents his work at National and International conferences.



Dr. Rachel Jimenez

Associate Program Director,
Harvard Radiation Oncology Residency Program,
Boston, MA,
USA

Dr. Rachel Jimenez, MD is an Assistant Professor at Harvard Medical School and a Breast Radiation Oncologist at Massachusetts General Hospital. She serves as the Department Associate Director of Translational Medicine and the Associate Residency Program Director. Her primary research interests are focused on the reduction of late toxicity associated with radiotherapy for breast cancer.

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Introducing International Speakers



Dr. Regis Resende Paulinelli

Mastology, Breast Oncoplastic Surgeon,
Federal University of Goias &
Araujo Jorge Hospital, Goiania, Goias,
Brazil

Dr. Regis Paulinelli made a specialization in Mastology in Brazil and fellowships in Breast Surgery and in Reconstructive Surgery in Italy, England and Germany. He is an International reference in Breast and Oncoplastic Surgery, a reviewer for many journals, has authored and co-authored dozens of scientific papers and book chapters. He authored his own textbook on Oncoplasty and Breast reconstruction in Brazil.



Dr. Raghavan Vidya

Consultant Oncoplastic Breast Surgeon,
Royal Wolverhampton Hospital &
Spire Little Aston Hospital, Birmingham,
UK

Dr. Vidya Raghavan perform breast surgery incorporating oncoplastic techniques and breast reconstruction with special interest in oncoplastic breast surgery and minimal axillary surgery.

She has been part of a multi-centre European Group in pioneering new method breast reconstruction- “Muscle Sparing Breast Reconstruction (Flip and Flop Technique)” which is relatively painless. She has also been a part of various breast cancer research projects.

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Introducing International Speakers



Dr. Apurna Jegannathen

Clinical Oncologist,
University Hospital of North Midlands &
The Nuffield Health North Staffordshire Hospitals,
UK

Dr. Jegannathen is the former Clinical Director for cancer services at the University Hospital of North Midlands (UHNM). Dr. Jegannathen currently holds the position of SABR lead and lung cancer lead at UHNM and has held the Clinical Director Post for Oncology, Haematology, Palliative Care and Immunology. Alongside her clinical work Dr. Jegannathen is actively involved in clinical research and principal investigator on many trials in lung and breast cancer and has published numerous articles in peer-reviewed journals.



Mr. Sankaran Narayanan

Consultant, Oncoplastic Breast Surgeon,
University Hospital, North Staffordshire,
UK

Mr. Narayanan has trained in General and Breast Surgery particularly in relevance to cancer and Onco-plastic Breast Surgery including Breast Reconstruction. He carried out his post graduate training in major cancer centres in London including Royal Marsden, Imperial College Health Care, Royal Free Hospital and University College Hospital (Middlesex).

Mr. Narayanan has a special interest in breast disease, diagnosis and management including Breast Reconstruction.

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Introducing International Speakers



Dr. Giuseppe Curigliano

Professor, Medical Oncologist,
University of Milano & HOD, Early Drug
Development, European Institute of Oncology,
Italy

Dr. Curigliano has served as a member of the ESMO Breast Cancer Faculty since 2001 and he is currently the faculty co-ordinator. He has also served on the scientific committee & co-chaired for the st. Gallen conference, esmo breast cancer congress and impakt esmo meeting. He has been an editorial board member for high impact oncology journals. He also serves on the european school of oncology (eso) faculty committee. Dr. Curigliano serves esmo as the chair of the guidelines committee and is a council member.

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National faculty



Dr. Anagha Zope

Senior Consultant,
Oncoplastic Breast Surgery,
Apollo Hospital, Ahmedabad



Dr. Anil Anand

Senior Director &
HOD, Radiation Oncology,
Fortis Memorial Research
Institute, Delhi



Dr. Aparna Dhar

HOD - Medical Genetics &
Genetic Counseling,
Corediagnostics, Haryana



Dr. Bhargavi Ilangovan

Senior Radiation Oncologist,
Madras Cancer Care
Foundation, Apollo Hospitals,
Chennai



Dr. Bidhu Mohanti

Director & Professor
Radiation Oncology,
Kalinga Institute of Medical
Sciences, Gurgaon



Dr. Gaurav Agarwal

Professor, Dept.
Endocrinology and Breast
Surgery, Sanjay Gandhi Post
Graduate Institute of Medical
Sciences, Lucknow



Dr. Geeta Kadayaprath

Head, Breast Surgical
Oncologist, Max Hospitals,
Delhi



Dr. Hiba Siddiqui

Senior Psycho-oncologist,
Max Healthcare,
Delhi-NCR



Dr. Jayanti Thumsi

Senior Consultant - Breast
Surgeon, Apollo Hospitals,
Bangalore



Dr. Jyoti Bajpai

Professor, Dept. of Medical
Oncology, Homi Bhabha
National Institute &
Tata Memorial Hospital,
Mumbai



Ms. Nishu Goel

Program Head- Kevat,
Patient Navigation,
International Liaison,
Communications, Media &
Publishing, TMC, Mumbai



Dr. Nita Nair

Professor, Dept of Surgical
Oncology, Breast Unit, Homi
Bhabha National Institute &
Tata Memorial Hospital, Mumbai

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National faculty



Dr. Nitesh Rohatgi

Senior Director Medical
Oncologist, Fortis Memorial
Research Institute,
Gurugram



Dr. Prabha Yadav

Director and Consultant,
Plastic and Reconstructive
Surgery, Sir H.N. Reliance
Hospital, Mumbai



Dr. Priya Tiwari

Senior Consultant Medical
Oncologist, Artemis
Hospital, Gurugram



Dr. Rajesh Balakrishnan

Professor, Dept. of
Radiation Oncology,
Christian Medical College,
Vellore



Dr. Rosina Ahmed

Consultant Breast Surgeon,
Tata Medical Center,
Kolkata



Dr. Selvi Radhakrishna

Senior Consultant
Oncoplastic Surgeon,
Chennai Breast Centre,
Chennai



Dr. Senthil Rajappa

Senior Consultant Medical
Oncologist, Basavatarakam Indo
American Cancer Hospital &
Research Institute, Hyderabad



Dr. Shona Nag

Director of Oncology,
Senior Consultant Medical
Oncologist, Sahyadri Group
of Hospitals, Pune



Dr. Somashekhar

Head and Consultant
Surgical Oncologist,
Manipal Hospitals, Bangalore



Dr. Sudeep Gupta

Director, ACTREC,
Professor, Medical Oncology,
Tata Memorial Centre, Mumbai



Dr. SVS Deo

Professor & Head,
Department of Surgical
Oncology, AIIMS, New Delhi



Dr. Swarupa Mitra

Senior Consultant & Chief of
Gastrointestinal & Genitourinary
Radiation Oncology,
Rajiv Gandhi Cancer Institute,
New Delhi

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National faculty



Dr. Tabassum Wadasadawala

Associate Professor, Dept. of Radiation Oncologist, Homi Bhabha National Institute & Tata Memorial Hospital, Mumbai



Dr. Uttam Soni

Consultant Oncoplastic Breast Surgeon, Breast & Cancer Research Institute, Sita Devi Hospital, Jaipur



Dr. Vaishali Zamre

Senior Consultant and Unit Head, Breast Disease Management Group, Max Hospitals, Delhi



Dr. Vani Parmar

Professor, Breast Surgeon, ACTREC, Navi Mumbai



Dr. Vinay Deshmane

Senior Consultant Surgical Oncologist & Specialist in Breast Diseases, Breach Candy Hospital & P.D. Hinduja Hospital, Mumbai



Dr. Vinay Ural

Senior Consultant Radiation Oncologist, Apollo Hospital, Banerghatta, Bangalore



Dr. Vineeta Goel

Senior Consultant Radiation Oncologist, Fortis Memorial Research Institute, Delhi

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30th October, 2021 | Day 1

Scientific Program

17:00 - 17:05 Welcome & Introduction

Speaker: Dr. Manjula Rao

17:05 - 17:10 Opening Remarks

Speaker: Ms. Preetha Reddy

(Executive Vice Chairperson, Apollo Hospitals)

Chairpersons: Dr. Vani Parmar,
Dr. Selvi Radhakrishna

17:10 - 17:30 Axillary Conservation, Post Neoadjuvant
Treatment - Wishful Thinking in the Indian
Setting ?

Speaker: Dr. Geeta Kadayaprath

Chairpersons: Dr. Anil Anand, Dr. Vinay Ural

17:30 - 17:50 Regional Nodal Irradiation in the Times of
SLNB & Neoadjuvant Systemic Treatments

Speaker: Dr. Sapna Nangia

Chairpersons: Dr. Jayanti Thumsi,
Dr. Apurna Jegannathan

17:50 - 18:10 Is 5 Fraction Breast Radiotherapy going to be
the New Standard of Care ?

Speaker: Dr. Rajesh Balakrishnan

Chairpersons: Dr. Bidhu Mohanti,
Dr. Ramesh Sarin

18:10 - 18:35 Proton Therapy for Breast Cancer:
The Consensus in 2021

Speaker: Dr. Rachel Jimenez

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30th October, 2021 | Day 1

Scientific Program

18:35 - 18:55 **This Session is Supported by Roche**
Neoadjuvant treatment of HER2+ve Early Breast Cancer

Speaker: Dr. Bhawna Sirohi

Chairpersons: Dr. Jyoti Bajpai,
Dr. Nitesh Rohatgi

18:55 - 19:15 **This Session is Supported by Lilly**
Sequencing Treatment Options for ER Positive ABC in a Resource Limited Setting

Speaker: Dr. Senthil Rajappa

Chairpersons: Dr. Anagha Zope,
Dr. Sudeep Gupta

19:15 - 19:35 Making Sense of all Options for Early TNBC
Speaker: Dr. Shona Nag

19:35 - 19:40 Closing Remarks
Speaker: Dr. Manjula Rao

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31st October, 2021 | Day 2

Scientific Program

17:00 - 17:05 Welcome

Speaker: Dr. Manjula Rao

17:05 - 17:10 Opening Address

Speaker: Mr. Harshad Reddy
(Director - Operations, APCC)

17:10 - 17:15 Intimacy Clinic Introduction

Speaker: Dr. Bhawna Sirohi

17:15 - 17:20 Intimacy Clinic Inauguration

Speaker: Dr. R.A. Badwe

Chairpersons: Dr. SVS Deo,
Dr. R.A. Badwe, Dr. G.K. Rath

17:20 - 17:40 Breast Conservation in Multicentric Breast Cancers

Speaker: Dr. Vinay Deshmane

Chairpersons: Mr. Sankaran Narayanan
Dr. Gaurav Agarwal

17:40 - 18:10 **Debate:** Extreme Oncoplasty for Breast Cancer - Apt Solution for Indian Setting?

For: Dr. Raghavan Vidya

Against: Dr. Somashekhar

Chairpersons: Mr. Sankaran Narayanan,
Dr. Uttam Soni, Dr. Vaishali Zamre

18:10 - 18:35 Novel Techniques in Oncoplasty - Geometric Compensation

Speaker: Dr. Regis Resende Paulinelli

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31st October, 2021 | Day 2

Scientific Program

Chairpersons: Dr. Prabha Yadav,
Dr. Ramesh Sarin

18:35 - 19:00 Post-Mastectomy Breast Reconstruction in the Indian Scenario - Current Perspective & Future Possibilities

Speaker: Mr. Venkat Ramakrishnan

Chairpersons: Dr. Vineeta Goel,
Dr. Apurna Jegannathan

19:00 - 19:20 Oncoplasty, Reconstruction & Breast Radiotherapy

Speaker: Dr. Tabassum Wadasadawala

19:20 - 19:50 Panel Discussion: Hereditary Breast Cancer
Moderator: Dr. Bhawna Sirohi

Panelists: Dr. Priya Tewari,
Dr. Nita Nair,
Dr. Aparna Dhar,
Dr. Bhargavi Ilangovan,
Dr. Hiba Siddiqui,
Dr. Rosina Ahmed,
Dr. Giuseppe Curigliano (Italy),
Dr. Shona Nag,
Dr. Swarupa Mitra,
Ms. Nishu Goel

19:50 - 19:55 Closing Remarks

Speaker: Dr. Manjula Rao

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REAL EARLY HER

Neoadjuvant PERJETA-Trastuzumab plus chemotherapy*: part of a complete, efficacious treatment regimen for HER2-positive eBC in the curative setting^{1,2}

In the neoadjuvant setting You can now do more for your HER2-positive eBC patients¹



An estimated 1 in 4 women with HER2-positive eBC will experience disease recurrence or death, even with the advances made by Herceptin³



eBC treatment has *curative* intent; therefore, it is important to give women the most efficacious treatment as early as possible⁴



A total of 18 cycles (1 year) of HER2-targeted therapy is the standard of care in the eBC setting, regardless of the timing of surgery and irrespective of pCR status⁵⁻⁸



Dual HER2 blockade with the PERJETA-Herceptin combination plus chemotherapy* offered patients:
— Nearly doubled pCR in the breast and lymph nodes, as seen in the NeoSphere trial¹
— pCR rate of more than 60%, as seen in the TRYPHAENA trial¹
— A consistent safety profile established across neoadjuvant, adjuvant, and metastatic settings^{1,9-12}

References: 1. PERJETA® Summary of Product Characteristics. © Hoffmann-La Roche Ltd, Basel, Switzerland, 2017. 2. Cortazar P, Zhang L, Untch M, et al. Pathological complete response and long-term clinical benefit in breast cancer: the CTNeoBC pooled analysis [published online February 14, 2014]. *Lancet*. 2014;384:164-172. doi:10.1016/S0140-6736(13)62248-3. 3. Slamon D, Eiermann W, Robert N, et al. for the BCIRG 006 Investigators. BCIRG 006 phase III trial comparing AC—T with AC—TH and with TCH in the adjuvant treatment of HER2-amplified early breast cancer patients: 10-year follow-up analysis. Presented at: 38th Annual San Antonio Breast Cancer Symposium (SABCS); December 8-12, 2015; San Antonio, TX. 4. Baselga J, Coleman RE, Cortés J, Janni W. Advances in the management of HER2-positive early breast cancer. *Crit Rev Oncol Hematol*. 2017;119:113-122. 5. Cugliandolo G, Burstein HJ, Winer EP, et al. for the Panel Members of the St. Gallen International Expert Consensus on the Primary Therapy of Early-Breast Cancer 2017. De-escalating and escalating treatments for early-stage breast cancer: the St. Gallen International Expert Consensus Conference on the Primary Therapy of Early-Breast Cancer 2017. *Ann Oncol*. 2017;28:1700-1712. 6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V2.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed October 15, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org. 7. Arbeitsgemeinschaft Gynäkologische Onkologie E.V. Diagnosis and treatment of patients with primary and metastatic breast cancer. *Guidelines Breast Version 2018.1*. <https://www.agg-onkologie.de/en/guidelines-mamma/march-2018/>. Updated 2018. Accessed February 26, 2019. 8. Ayala de la Peña R, Andrés R, García-Sanz JA, et al. SEOM clinical guidelines in early stage breast cancer (2018). *Clin Transl Oncol*. 2018. doi:10.1007/s12094-018-1972-9. 9. Ganni L, Pierikowski T, Jin Y-H, et al. Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): a randomised multicentre, open-label phase 2 trial. *Lancet Oncol*. 2012;13:25-32. 10. Schneeweiss A, Chia S, Hickish T, et al. Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: a randomized phase II cardiac safety study (TRYPHAENA). *Ann Oncol*. 2013;24:2778-2784. 11. Baselga J, Cortés J, Kim S-B, et al. for the CLEOPTRA Study Group. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. *N Engl J Med*. 2012;366:109-119. 12. von Minckwitz G, Procter M, de Azavedo J, et al. for the APHINITY Steering Committee and Investigators. Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer [published online June 5, 2017]. *N Engl J Med*. 2017;377:122-131. doi:10.1056/NEJMoa1703643.

ABBREVED PRESCRIBING INFORMATION - Pertuzumab Injection (Perjeta®)
Generic Name: Pertuzumab Injection 420mg/1.4mL **Brand name:** Perjeta® **Indications:** HER2-positive Metastatic Breast Cancer: Pertuzumab is indicated in combination with Trastuzumab and Docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not yet received any chemotherapy for their metastatic disease. **HER2-positive Early Breast Cancer:** Pertuzumab is indicated in combination with Trastuzumab and Chemotherapy for the neoadjuvant treatment of patients with HER2-positive, locally advanced inflammatory or early stage breast cancer (either 2 cm or diameter or node-positive) as part of a complete treatment regimen for early breast cancer. Pertuzumab is indicated for use in combination with Trastuzumab and chemotherapy for adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. **Type of Dosage form:** Sterile concentrate for solution for infusion. Perjeta is supplied as a single-use vial containing 1.4 mL preservative free liquid concentrate, at an active ingredient (Pertuzumab) concentration of 30 mg/mL. **Dosage and administration:** Perjeta therapy should only be administered under the supervision of a healthcare professional experienced in the treatment of cancer patients. Perjeta must be diluted by a healthcare professional and administered as an intravenous infusion. Use a sterile needle and syringe for withdrawing appropriate amount of solution from the vial. Do not administer as an IV push or bolus. **HER2-positive Metastatic Breast Cancer and HER2-positive Early Breast Cancer:** The recommended initial dose of Perjeta is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by a dose of 420 mg administered over a period of 30 to 60 minutes. An observation period of 30 to 60 minutes is recommended after completion of each Perjeta infusion. The observation period should be completed prior to any subsequent dose of Trastuzumab chemotherapy. Perjeta and Trastuzumab should be administered sequentially and can be given in any order. When administered with Perjeta, the recommendation is to follow a 3 weekly schedule for trastuzumab administered as an IV infusion with an initial dose of 8 mg/kg followed every 3 weeks thereafter by a dose of 6 mg/kg body weight in patients receiving Trastuzumab and Trastuzumab should be administered prior to the 3 weekly schedule. When administered with Perjeta, the recommended initial dose of docetaxel is 75 mg/m². In patients receiving an anthracycline-based regimen, Perjeta and Trastuzumab should be administered following completion of the entire anthracycline regimen. **HER2-Positive Metastatic Breast Cancer (MBC):** Perjeta should be administered in combination with Trastuzumab and docetaxel until disease progression or unacceptable toxicity. Treatment with Perjeta and Trastuzumab may continue even if treatment with docetaxel is discontinued. **HER2-Positive Early Breast Cancer (eBC):** In the neoadjuvant setting (before surgery), Perjeta should be administered with Perjeta for three to six cycles depending on the regimen chosen in combination with Trastuzumab and chemotherapy (see full prescribing information for detailed information). In the adjuvant setting (after surgery), Perjeta should be administered in combination with Trastuzumab for a total of one year (maximum 18 cycles or until disease recurrence or unacceptable toxicity, whichever occurs first), as part of a complete regimen for early breast cancer, including standard anthracycline and/or taxane-based chemotherapy. Perjeta and Trastuzumab should start on Day 1 of the first cycle containing cycle and should continue even if chemotherapy is discontinued (see full prescribing information for detailed information). **Delayed or missed doses:** If the time between two sequential infusions of Perjeta is less than 6 weeks, the 420 mg dose of Perjeta should be administered as soon as possible. Do not wait until the next planned dose. If the time between two sequential infusions of Perjeta is 6 weeks or more, the initial dose of 840 mg Perjeta should be administered as a single intravenous infusion followed by a maintenance dose of 420 mg. Perjeta administered over a period of 30 to 60 minutes every 3 weeks thereafter (see full prescribing information for detailed information). **Dose modifications:** Perjeta should be discontinued if Trastuzumab treatment is discontinued. Dose reductions are not recommended for Perjeta and Trastuzumab (see Trastuzumab full prescribing information). For chemotherapy dose modifications, see relevant prescribing information. **Special dosage instructions:** Pediatric use: The safety and efficacy of Perjeta in children and adolescents below 18 years of age have not been established. Geriatric use: No dose adjustment is required in patients ≥ 65 years of age. Renal impairment: Dose adjustment of Perjeta are not needed in patients with mild or moderate renal impairment. No dose recommendations can be made for patients with severe renal impairment because of the limited pharmacokinetic data available. Hepatic impairment: The safety and efficacy of Perjeta have not been studied in patients with hepatic impairment. **Contraindications:** Perjeta is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its ingredients. **Warnings and Precautions:** **Left ventricular dysfunction:** Decreases in LVEF have been reported with drugs that block HER2 activity, including Perjeta. The incidence of asymptomatic left ventricular systolic dysfunction (LVSD) (congestive heart failure) was higher in patients treated with Perjeta in combination with Herceptin and chemotherapy compared with Herceptin and chemotherapy. Patients who have received prior anthracycline or prior radiotherapy to the chest area may be at higher risk of decreased LVEF. The majority of cases of symptomatic heart failure reported in the adjuvant setting were in patients who had received anthracycline-based chemotherapy. Assess LVEF prior to initiation of Perjeta and at regular intervals of 1-2 weeks during treatment to ensure that LVEF is within normal limits. If the LVEF declines and has not improved or has declined further at the subsequent assessment, discontinuation of Perjeta and trastuzumab should be strongly considered unless the benefit for the individual patient is deemed to outweigh the risks. For Dose recommendations for left ventricular dysfunction, refer to Table 2 of full Prescribing Information. **Infection-related reactions:** Perjeta has been associated with infection-related reactions, including events with fatal outcomes. Close observation of the patient during and for 60 minutes after the first infusion and during and for 30 minutes following subsequent infusions of Perjeta is recommended. If a significant infection-related reaction occurs, the infusion should be slowed down and promptly and appropriate medical therapy should be administered. Patients should be evaluated and carefully monitored until complete resolution of signs and symptoms. Permanent discontinuation should be considered in patients with severe infection reactions. This clinical assessment should be based on the severity of the preceding reaction and response to administered treatment for the adverse reaction (see full prescribing information for detailed information). **Hypersensitivity reactions/anaphylaxis:** Patients should be observed closely for hypersensitivity reactions. Severe hypersensitivity reactions, including anaphylaxis and events with fatal outcomes, have been observed in patients treated with treatment of Perjeta. Perjeta is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its ingredients. **Use in Special Population:** **Contraception:** Women of child bearing potential, including those who are partners of male patients, should use effective contraception while receiving Perjeta and for 6 months following the last dose of Perjeta. **Pregnancy:** Perjeta should be avoided during pregnancy unless the potential benefit for the mother outweighs the potential risk to the fetus. There are no studies of Perjeta in pregnant women. Perjeta administered to pregnant women during organogenesis led to oligohydramnios, delayed renal development and early fetal death. Therefore, based on these animal studies and the mechanism of action, Perjeta is considered to have the potential to cause fetal harm when administered to pregnant women. **Label and delivery:** The safe use of Perjeta during label and delivery has not been established. **Lactation:** Because human IgG is secreted in human milk and the potential for absorption and harm to the infant is unknown, a decision should be made to discontinue nursing or the Perjeta treatment, taking into account the importance to the mother and the elimination half-life of pertuzumab (see full prescribing information for detailed information). **Pediatric use:** The safety and efficacy of Perjeta in children and adolescents below 18 years of age have not been established. **Geriatric use:** No overall differences in efficacy of Perjeta were observed in patients ≥ 65 and < 65 years of age. **Undesirable Effects:** This is not the complete list from Clinical Trials. HER2-positive Metastatic and HER2-positive Early Breast Cancer: Perjeta is used with Trastuzumab and chemotherapy. It is difficult to ascertain the causal relationship of an adverse reaction to a particular drug. The safety of Perjeta was generally consistent across studies, although the incidence and most common adverse drug reactions (ADRs) varied depending on whether Perjeta was administered as monotherapy or in combination with other anti-neoplastic agents. The most common ADRs (≥ 10%) from pooled data (clinical trials in HER2-positive MBC and eBC) were diarrhea, alopecia, nausea, fatigue, neutropenia, and vomiting. The most common ADRs (≥ 10%) were neutropenia and fatigue. Other very commonly reported adverse reactions include asthenia, headache, lymphopenia, decreased appetite, constipation, dyspnea, abdominal pain, mucosal inflammation, arthralgia, myalgia, pain in extremities, dysgeusia, malaise, reports and laboratory tests. **Interactions with other modified products and other forms of interaction:** A study in 17 patients in the phase II CLEOPTRA showed no evidence of drug-drug interaction between Perjeta and Herceptin and between Perjeta and docetaxel. In addition, no clinically relevant pharmacokinetic interaction of co-administered docetaxel or Trastuzumab on Perjeta was evident, based on the population pharmacokinetics analysis. This lack of drug-drug interaction was confirmed by pharmacokinetic data from the NeoSphere and APHERITY study. Five studies have evaluated the effects of Perjeta on the pharmacokinetics of co-administered cytosolic agents, docetaxel, paclitaxel, peritaxel, carboplatin, carboplatin, and irinotecan. There was no evidence of any pharmacokinetic interaction between Perjeta and any of these agents. The pharmacokinetics of Perjeta in these studies was comparable to those observed in single-agent studies. **Overdose:** There is no experience with overdose in human clinical trials. Single doses higher than 21 mg/kg (172 mg) have not been tested. **Storage Conditions:** Store in a well-protected, light-resistant container at 2°C - 8°C. Keep vial in the original carton to protect from light. Do not freeze. Do not shake. Shelf life 24 months. This medicine should not be used after the expiry date shown on the pack. **Self-life:** The solution for infusion containing the preservative Perjeta does not contain any antimicrobial preservatives; therefore, care must be taken to ensure the sterility of the prepared solution. The solution of Perjeta for infusion diluent is polypropylene (PP) or non-PP polypropylene bag containing 0.9% Sodium Chloride Injection, USP. Perjeta must be stored at 2°C - 8°C. Perjeta is stable for up to 24 hours prior to use. Diluted Perjeta has been shown to be stable for up to 24 hours up to 30°C. However, once diluted Perjeta should be stored refrigerated (2°C - 8°C). Perjeta is a single-use vial of 1.4mL containing 420mg of pertuzumab (30mg/mL). Please read full prescribing information before use. **Details of Permission or License Number with date:** MP/275/2014 dated 29 December 2014. **Date of Revision:** current as of March 2021, Version 1.2.0

eBC = early breast cancer; FEC=5-fluorouracil + epirubicin + cyclophosphamide; HER2=human epidermal growth factor receptor 2; PH=PERJETA-Herceptin.

*Standard options in the registrational trials included PH + docetaxel (4 cycles) (NeoSphere); PH + docetaxel + carboplatin (6 cycles); FEC (3 cycles) followed by PH + docetaxel (3 cycles); PH + FEC (3 cycles) followed by PH + docetaxel (3 cycles) (TRYPHAENA).

There is insufficient evidence to recommend concomitant administration of an anthracycline with PERJETATM.

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