



PRESENTS

8TH NATIONAL ANNUAL CONFERENCE **ISMPOCON 2022**

DATE: 28TH - 30TH JAN, 2022

**SEQUENCING OLD AND NEW THERAPIES
TO TRANSFORM TREATMENT PARADIGMS**

MMC has Granted 7 CME Credit Points

Organizing Chairpersons



Dr. Govind Babu



Dr. Sudeep Gupta

Organizing Secretaries



Dr. B. K. Smruti



Dr. Jyoti Bajpai



Dr. Kumar Prabhash



Dr. Manju Sengar

Scientific Committee Chair

Click on the link below for registration:

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WELCOME ADDRESS

Dear Sir/Madam,

The Indian Society Of Medical and Paediatric Oncology (ISMPO) is pleased to invite you to its **8th National Annual Conference titled ISMPOCON 2022 to be held on 21st - 23rd Jan and 28th - 30th Jan 2022.**

The conference theme is “Sequencing old and new therapies to transform treatment paradigms” in common malignancies.

Given the current pandemic situation, the conference will be held on a virtual platform.

Renowned international and national faculty will be discussing cutting-edge rare cancer management, rare aspects of common cancers and therapy sequencing to enhance the quality of care. The gap will be bridged through engaging Panel Discussions and comprehensive tumor boards.

We look forward to your participation.

Regards,

Organizing Chairpersons

Dr. Govind Babu
Dr. Sudeep Gupta

Scientific Committee Chair

Dr. Kumar Prabhash
Dr. Manju Sengar

Organizing Secretary

Dr. B.K. Smruti
Dr. Jyoti Bajpai

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HIGHLIGHTS OF THE MEETING

- Management of Rare Cancers
- Management of Rare Situations in Common Cancers
- Optimizing Sequencing with Old and New Therapies
- What's New in Adjuvant and Neo-adjuvant Therapies
- Multidisciplinary Tumor Boards
- Oral Presentation/Poster Presentation with Awards
- Quiz Competition with Attractive Awards
- Expanding the Reach of ISMPO through New Strategies
- Women's Oncology Forum

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INTERNATIONAL FACULTY



Dr. Nitin Jain

Associate Professor,
Department of Leukemia,
MD Anderson Cancer Center
Houston, Texas



Dr. Natasha B Leigh

Lung Site Lead, Medical Oncology,
Princess Margaret Cancer Centre,
Professor, Department of Medicine,
University of Toronto, Toronto



Dr. Ranjana Advani

Medical Oncologist,
Saul Rosenberg Professor of
Lymphoma,
Stanford Health Care, California



Dr. Solange Peters

ESMO President,
Chair, Medical Oncology,
Oncology Department - CHUV
Lausanne University, Switzerland



Dr. Fatima Cardoso

Director, Breast Unit
Champalimaud Clinical Center,
Lisbon, Portugal



Dr. Lizza Hendriks

Post-Doctorate,
Maastricht University Medical
Centre - Pulmonary Diseases,
Maastricht, Netherlands



Dr. Milind Javle

Professor, GI Medical Oncology,
The University of Texas,
MD Anderson Cancer Center,
Houston, Texas, USA



Dr. Susana Banerjee

Consultant Medical Oncologist,
Research Lead,
The Royal Marsden NHS
Foundation, London, UK



Dr. Tony Mok

Chairman,
Department of Clinical Oncology,
Hong Kong



Dr. Everett E. Vokes

President - American Society of
Clinical Oncology, University of
Chicago Medicine and
Biological Sciences, USA

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Scientific Program | Day 4 | 28th January 2022

Time	Topic
16:15 - 17:15	Main Oral Presentation Judges: Dr. NK Warriar, Dr. Shekhar Patil
	Industry Symposium
	Supported by Astrazeneca
17:15 - 17:45	"Redefining the management of Her2 negative early breast cancer in the era of precision medicine". Speaker: Dr. Tejinder Singh
17:45 - 17:50	Welcome & Introduction: Dr. Sudeep Gupta, Dr. Govind Babu
17:50 - 17:55	Chairpersons: Dr. Kannan Kalaichelvi, Dr. Babita Hapani, Dr. Govind Babu
	Session 1: Breast Cancer Symposium
17:55 - 18:25	Complexities to consensus : Highlights from ABC6 Guidelines Speaker: Dr. Fatima Cardoso
18:25 - 18:35	Q & A Lead Discussant: Dr. B K Smruti
18:35 - 18:50	Triple positive breast cancer an enigma Speaker: Dr. B K Smruti
	Session 2 : ISMPO ESMO Lung Symposium
	Chairpersons: Dr. Digambar Behera, Dr. Lizza Hendriks, Dr. Vijay Anand Reddy
18:50 - 19:05	Immunotherapy in advance NSCLC :Is Newer data of value or repetition? Speaker: Dr. Solange Peters
19:05 - 19:15	Q & A
19:15 - 19:25	Second line therapy after Immunotherapy – Are there any specific choices? Speaker: Dr. TVS Tilak
19:25 - 19:35	Biomarker in Immunotherapy – Are all of them required? Speaker: Dr. Navneet Singh

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	Chairpersons: Dr. Pankaj Shah, Dr. Shuaib Zaidi
19:35 - 19:50	Is Resistance to 3rd Gen TKI in 1st Line Fuelling New Therapeutic Strategies? Speaker: Dr. Tony Mok
19:50 - 20:05	Evolving landscape of novel oncogenic drivers in NSCLC and therapies: Beyond the conventional Speaker: Dr. Natasha Leighl
20:05 - 20:15	EGFR and ALK mutation positive Lung cancer – How is the outcome for Indian patients? Speaker: Dr. Kumar Prabhash
20:15 - 20:30	The brain metastasis in NSCLC: Are current therapies changing the treatment paradigms? Speaker: Dr. Lizza Hendriks
20:30 - 20:40	Endpoints in Adjuvant trials in Immunotherapy and targeted therapy – Is this the way to go? Speaker: Dr. Prabhat Malik
	Chairpersons: Dr. Natasha Leighl, Dr. R K Deshpande, Dr. J P Agarwal
20:40 - 21:10	Panel Discussion : Real world perspective on immunotherapy in NSCLC “implementing state of the art in the clinic” Moderator: Dr. Ullas Batra Panelists: Dr. Natasha Leighl, Dr. Vashishta Maniar, Dr. Senthil Rajappa, Dr. Anvesh Rathore, Dr. Kumardeep Dutta, Dr. Abhishek Mahajan, Dr. Navneet Singh, Dr. Deepam Pushpam
21:10 - 21:40	Panel Discussion: Real world perspective on oncogene driven NSCLC “Implementing precision oncology in the clinic” Moderator: Dr. Vanita Noronha Panelists: Dr. Natasha Leighl, Dr. Anil Tibdewal, Dr. George Karimundackal, Dr. Shivam Shingla, Dr. Anuradha Choughule, Dr. Bhuvan Chugh, Dr. Narayanan Prasad, Dr. Priyanka Srivastava, Dr. Prabhat Malik, Dr. TVSGVK Tilak

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Scientific Program | Day 5 | 29th January 2022

Time	Topic
08:30 - 09:30	QUIZ Quiz Coordinators: Dr. Pritam Kataria, Dr. B. Suresh Kumar This session is sponsored by MSD
09:30 - 10:00	Role of Immunotherapy in 1 st line unresectable recurrent or Metastatic Head & Neck squamous cell carcinoma Speaker: Dr. Aditya Murli
	Sesion 3: Multidisciplinary Tumor Board Chairpersons: Dr. Lokanatha Dassappa, Dr. K. Sambasivaiah
10:00 - 10:30	Case of Metastatic NSCLC Lead Discussant: Dr. Sajjan Rajpurohit & Dr. Rashmi Bansal Expert Panelist: Dr. Bhupesh Guleria, Dr. K V Krishnamani, Dr. V. Arumugam, Dr. Wesely Jose, Dr. Davindar Paul, Dr. Rakesh Reddy Boya, Dr. Arun Warriar, Dr. Prriya Eshpuniyani
10:30 - 11:00	Case of Metastatic RCC Lead Discussant: Dr. Chandan K Das & Dr. Jatin Chaudhari Expert Panelist: Dr. Vivek Belathur, Dr. Rakesh Roy, Dr. P. Suresh, Dr. Abhishek Kakroo, Dr. Sujith M, Dr. P. K. Jayachandran, Dr. Venkat Vivek, Dr. Tarachand Gupta
	Chairpersons: Dr. Jagdeep Singh, Dr. Meher Laksmi
11:00 - 11:30	Case of Metastatic Colorectal Cancer Lead Discussant: Dr. Viraj Lavingia Expert Panelist: Dr. Harshvardhan Atreya, Dr. Amol Dongre, Dr. Udip Maheshwari, Dr. B Sainath, Dr. Venkat Pradeep Babu Koyalla, Dr. Vidya Veldore, Dr. Rohit Swami, Dr. Naresh Jadhav

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Time	Topic
11:30 - 12:00	Case of Metastatic Ovarian Cancer Lead Discussant: Dr. Anita Ramesh Expert Panelist: Dr. Smitha Saldanha, Dr. Ajay Yadav, Dr. Siddharth Turkar, Dr. Krishnakumar Rathnam, Dr. Sourabh Radhakrishnan, Dr. Anubha Bharthuar, Dr. Amita Maheshwari, Dr. Nadeem Shouket
12:00 - 13:00	Main Oral Presentation Judges: Dr. Shekhar Patil, Dr. Sudeep Gupta, Dr. N. K. Warriar, Dr. Hemant Malhotra
13:00 - 14:00	Industry Symposium Supported by Astrazeneca
13:00 - 13:15	Experience sharing on Durvalumab in ES-SCLC Speaker: Dr. Chintan Shah
13:15 - 13:30	Real world Evidence Osimertinib as SoC in the management of EGFRm NSCLC Speaker: Dr. Amit Rauthan Supported by Roche
13:30 - 14:00	Deep dive into clinical practice of unresectable HCC: Managing patients with Atezolizumab Bevacizumab combination in Unresectable HCC Moderator: Dr. Ashish Joshi Panelists: Dr. Akshay Shivchand, Dr. Maheboob Basade, Dr. Tushar Patil, Dr. Suhas Agre, Dr. Samir Shah, Dr. Anup Toshniwal
	Session 4: GI Cancers Metastatic Colorectal Cancers Chairpersons: Dr. Devendra Pal, Dr. Deepak Chhabra
14:00 - 14:20	Do novel systemic approaches reset the clock for treatment selection and sequencing in mCRC Speaker: Dr. Dipanjan Panda
14:20 - 14:25	Q & A Lead Discussant: Dr. Ankur Bahl

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Scientific Program | Day 5 | 29th January 2022

Time	Topic
	Gastric & GE in Tumors
	Chairpersons: Dr. Sanjay Sharma, Dr. Rakesh Chopra Dr. Prashant Kerkar
14:25 - 14:40	Pushing the boundaries optimising survival with new strategies in HER2 +ve and negative disease Speaker: Dr. Krishna Prasad
14:40 - 14:50	New development in the therapeutic game plan for treatment of HCC Speaker: Dr. M. Vamshi Krishna
14:50 - 15:30	Panel discussion (mCRC/GEJ/Gastric Cancer): Real world perspective “Implementing state of art in the clinic” Moderator: Dr. Anant Ramaswamy Panelists: Dr. E Prasad, Dr. Muzzammil Shaikh, Dr. Sandip Ganguly, Dr. Chetan Deshmukh, Dr. Peush Bajpai, Dr. Anoop T M, Dr. Pradip Kumar Mondal, Dr. Burhan Wani
	Session 5 : Genitourinary Cancers: “New options rocking the boat”
	Chairpersons: Dr. Raju Titus Chacko, Dr. Hemang Bakshi, Dr. B A Krishna
15:30 - 15:55	Sequencing therapies in metastatic castration sensitive and resistant prostate cancer: Impact of new evidence and predictive markers Speaker: Dr. Chirag Desai
15:55 - 16:00	Q & A Lead Discussant: Dr. Vineet Talwar
16:00 - 16:15	New algorithms of treatment of mRCC in 1st and subsequent lines Speaker: Dr. T. Raja
16:15 - 16:30	Embarking on novel strategies on metastatic Bladder cancer : putting chemotherapy on the backburner Speaker: Dr. Bharat Vaswani

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Time	Topic
16:30 - 17:10	Panel discussion (GU cancers): Real world perspective “Implementing state of art in the clinic” Moderator: Dr. Chirag Desai Panelists: Dr. Tejinder Singh, Dr. Minish Jain, Dr. Rakesh Pinninti, Dr. Sandeep Jasuja, Dr. Rejiv Rajendranath, Dr. C T Satheesh, Dr. Indranil Ghosh, Dr. K. N. Parthasarthy
	Session 6 : GYNEC: “Incorporating Biomarkers , Novel Therapies and Combination Strategies” Chairpersons: Dr. Roshni Pandey, Dr. Vibha Naik
17:10 - 17:25	Ovarian Cancer: Personalised Medicine in Incorporating Novel Therapies Today and Tomorrow Speaker: Dr. Amit Agarwal
17:25 - 17:40	Endometrial Cancer: “Changing the Guard with Targeted Systemic Options and Immunotherapy”. Speaker: Dr. Susana Banerjee
17:40 - 17:45	Q & A Lead Discussant: Dr. B K Smruti
17:45 - 18:00	Cervical Cancer: What has changed now and what lies on the horizon Speaker: Dr. Sudeep Gupta Chairpersons: Dr. B. K. Mishra, Dr. G. S. Chowdhary
18:00 - 18:40	Panel Discussion (Gynecological Cancers): Real World Perspective “How Do I Treat” Moderator: Dr. Chanchal Goswami Panelists: Dr. A Preethi, Dr. Kakoli Lahakar, Dr. Bhavna Parikh, Dr. Suman Kalyan, Dr. Chetna Bakshi, Dr. Sandeep Batra, Dr. Mohit Saxena

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Scientific Program | Day 5 | 29th January 2022

Time	Topic
19:00 - 21:00	Poster Discussion Judges: Dr. Ramesh Nimmagadda, Dr. Ganapathy R Dr. Prakash Chitalkar
18:55 - 19:30	ISMPO ORATION Chairpersons: Dr. D. C. Doval, Dr. Shekar Patil Journey of A medical oncology in India - Opportunities Galore Speaker: Dr. Shyam Aggarwal Chairpersons: Dr. Maheboob Basade, Dr. Asha Kapadia
	ASCO ISMPO Joint Symposium
19:30 - 19:50	Advancing Equitable Cancer Care Through Innovation Speaker: Dr. Everett Vokes
19:50 - 20:05	Our problems our solutions Speaker: Dr. Govind Babu
	Industry Symposium
20:05 - 20:45	Supported by Lilly
20:45 - 21:30	Supported by Novartis
20:45 - 21:05	Redefining Overall Survival Speaker: Dr. Akhil Kapoor
21:05 - 21:30	Panel Discussion Moderator: Dr. MVT Krishna Mohan Panelists: Dr. E Prasad, Dr. Vinayak Makka, Dr. Pankaj Goel, Dr. Chandrakant MV, Dr. Kaushal Patel, Dr. Shivam Shingla, Dr. Arun Makka, Dr. Aparna Dhar

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Scientific Program | Day 6 | Hall A | 30th January 2022

Time	Topic
09:00 - 10:00	Quiz / Oral Presentation (BS) Quiz Co-ordinators: Dr. Hemanth Kumar, Dr. Rohit Pai Judges: Dr. Shona Nag, Dr. Raju Titus Chacko
10:00 - 12:00	Session 7: Neo/adjuvant therapies "whats new ?" Chairpersons: Dr. Ravi Divakar, Dr. Bhavesh Parekh, Dr. Anil Sanghvi
10:00 - 10:15	Neo/adjuvant therapies "whats new ?" in Breast cancer Speaker: Dr. Shona Nag
10:15 - 10:30	Neo/adjuvant therapies "whats new ?" in NSCLC Speaker: Dr. T P Sahoo
10:30 - 10:45	Neo/adjuvant therapies "whats new ?" in Renal Cell Carcinoma Speaker: Dr. Priya Tiwari
10:45 - 11:05	Neo/adjuvant therapies "whats new ?" in GEJ and Gastric Cancer Speaker: Dr. Ankur Bahl
11:05 - 11:10	Q & A
	Session 8 : GI Cancers Chairpersons: Dr. P. Jagannath, Dr. Ravi Mohan Dr. Vikas Ostwal
11:10 - 11:25	Treatment of pancreatic cancer: Looking below the tip of the Iceberg Speaker: Dr. Vishwanath S
11:25 - 11:55	Cholangiocarcinoma: "Precision Medicine Bearing Fruit" Speaker: Dr. Milind Javle
11:55 - 12:05	Q & A Lead Discussant: Dr. Ranga Rao
12:05 - 12:20	Gall bladder cancer: state of the art and future perspectives Speaker: Dr. Amol Patel

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Scientific Program | Day 6 | Hall A | 30th January 2022

Time	Topic
	Chairpersons: Dr. Surendra Beniwal, Dr. Shyam Agrawal
12:20 - 13:00	Panel Discussion (Advance Pancreatic/Choelngiocarcinoma/Gall Ballder Cancer): Real World Perspective” How Do I Treat” Moderator: Dr. Bhawna Sirohi Panelists: Dr. Dipanjan Panda, Dr. Ashish Joshi, Dr. Niti Raizada, Dr. Ravi Wategaonkar, Dr. Boman Dhabhar, Dr. Tanveer Maksud, Dr. K. H. Medhi, Dr. Rakesh Taran, Dr. Rahul Sud
13:00 - 13:15	Vote of Thanks and Valedictory
13:15 - 14:15	General Body Meeting

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Scientific Program | Day 6 | **Hall B** | 30th January 2022

Time	Topic
	Session 9: Haemto - lymphoid session
	Chairpersons: Dr. Shirish Alurkar, Dr. S. H. Advani
09:45 - 10:10	NLPHL- What is the best treatment pathway? Speaker: Dr. Ranjana Advani
10:10 - 10:15	Q & A Lead Discussant: Dr. Reshma Puranik
10:15 - 10:35	How to individualize the treatment of Mantle cell lymphoma Speaker: Dr. Prasanth Ganesan
10:35 - 10:45	Q & A Lead Discussant: Dr. Punit Jain
	Chairpersons: Dr. Bharat Parikh, Dr. Sunil Gupta
10:45 - 11:10	Management of CLL in 2022 Speaker: Dr. Nitin Jain
11:10 - 11:20	Q & A Lead Discussant: Dr. Hari Menon
	Chairpersons: Dr. Malay Nandy, Dr. SVSS Prasad
11:20 - 11:45	How best to incorporate the novel agents in the management of Newly diagnosed multiple myeloma: Interpretation of the available data Speaker: Dr. Pankaj Malhotra
11:45 - 11:55	Discussion Lead Discussant: Dr. Bhausahab Bagal
	Chairpersons: Dr. Rajeshwar Singh, Dr. Ramesh Nimmagadda
11:55 - 12:35	Panel discussion : Mature systemic T-cell lymphoma - what can we do for these patients Moderator: Dr. Manju Sengar Panelists: Dr. Hari Menon, Dr. Gaurav Prakash, Dr. Ghanshyam Biswas, Dr. Sandeep Shah, Dr. D K Mishra, Dr. Rajeew Vijayakumar, Dr. Prashant Mehta, Dr. Prakash N.P
12:35 - 12:40	Vote of thanks

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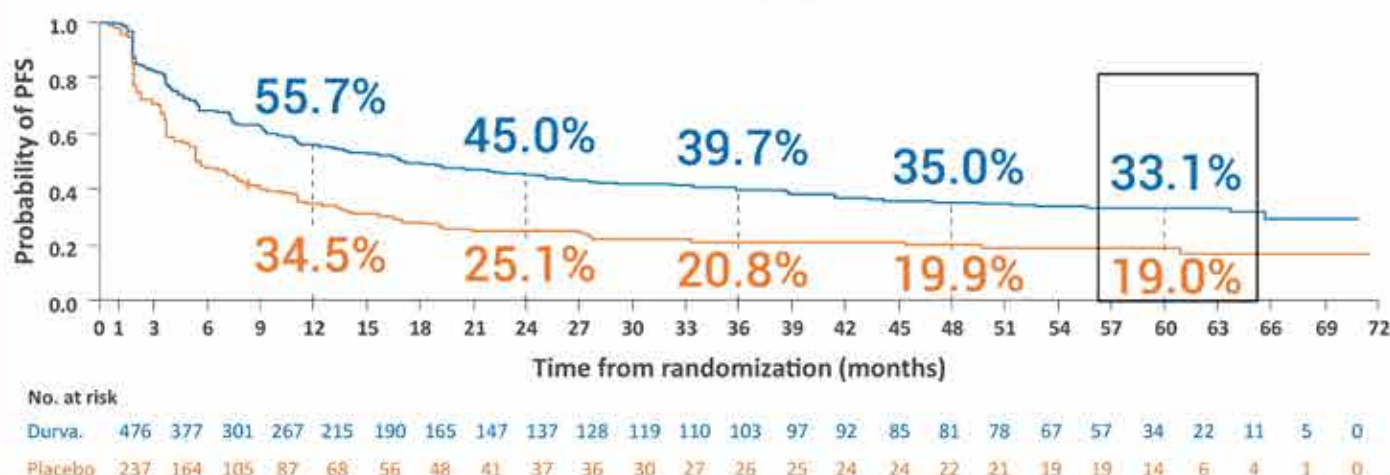


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BICR: Blinded independent central review; CI: Confidence interval; DCO: Data cutoff; HR: Hazard ratio; ITT: Intent-to-treat; PFS: Progression-free survival

Reference:

1. Spigel DR, et al. Poster presented at: ASCO Virtual Meeting, June 4–8, 2021.

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Primary analysis: median OS was not reached with TECENTRIQ® + Avastin® vs 13.2 months with sorafenib (HR=0.58; 95% CI, 0.42, 0.79; P=0.0006)¹

**42% reduced risk of death demonstrated with
atezolizumab + bevacizumab vs sorafenib¹**

Reference: 1, Finn R, et al. Atezolizumab plus bevacizumab in unresectable hepatocellular carcinoma. New England Journal of Medicine. 2020;382:1894-1905

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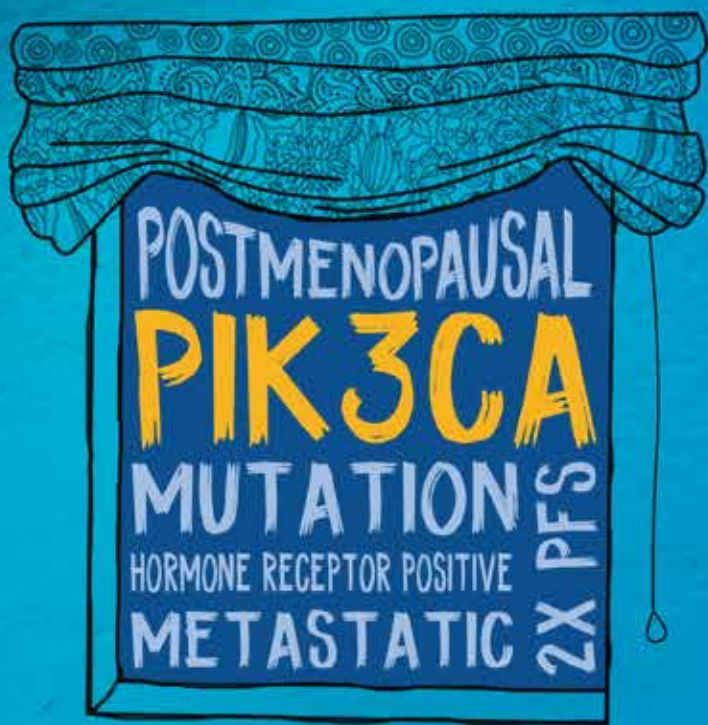
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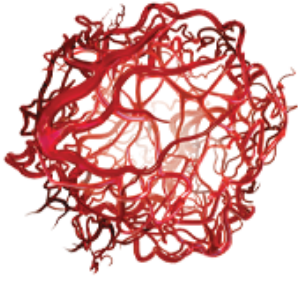
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Romiplostim



ABPI

Romiset (Romiplostim 125/250/500 mcg lyophilised powder for solution for injection)
COMPOSITION: Romiplostim 125 micrograms lyophilised powder for solution for injection: Each vial contains 125 mcg of romiplostim. After reconstitution, a deliverable volume of 0.25 ml solution contains 125 mcg of romiplostim (500 mcg/mL). Romiplostim 250 micrograms lyophilised powder for solution for injection: Each vial contains 250 mcg of romiplostim. After reconstitution, a deliverable volume of 1 ml solution contains 250 mcg of romiplostim (500 mcg/mL). Romiplostim 500 micrograms lyophilised powder for solution for injection: Each vial contains 500 mcg of romiplostim. After reconstitution, a deliverable volume of 1 ml solution contains 500 mcg of romiplostim (500 mcg/mL). **INDICATIONS:** Romiplostim is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). **POSODOGY AND METHOD OF ADMINISTRATION:** Treatment should remain under the supervision of a physician who is experienced in the treatment of haematological diseases. Romiplostim should be administered once weekly as a subcutaneous injection. Initial dose: The initial dose of romiplostim is 1 mcg/kg based on actual body weight. Dose calculation: The volume of romiplostim to administer is calculated based on body weight, dose required, and concentration of product. Dose adjustments: A subject's actual body weight at initiation of therapy should be used to calculate dose. The once weekly dose of romiplostim should be increased by increments of 1 mcg/kg until the patient achieves a platelet count $\geq 50 \times 10^9/L$. Platelet counts should be assessed weekly until a stable platelet count $\geq 50 \times 10^9/L$ for at least 4 weeks without dose adjustment has been achieved. Treatment discontinuation: Treatment with romiplostim should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after four weeks of romiplostim therapy at the highest weekly dose of 10 mcg/kg. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS AND PRECAUTIONS:** Recurrence of thrombocytopenia and bleeding after cessation of treatment. Thrombocytopenia is likely to recur upon discontinuation of treatment with romiplostim and there is an increased risk of bleeding in presence of anticoagulants or anti-platelet agents. Patients should be closely monitored for a decrease in platelet count and medically managed to avoid bleeding upon discontinuation of romiplostim. Thrombotic/thromboembolic complications: Platelet counts above normal range present a risk for thrombotic/thromboembolic complications. Caution should be used when administering romiplostim to patients with known risk factors for thromboembolism including but not limited to inherited (e.g. Factor V Leiden) or acquired risk factors (e.g. ATII deficiency, antiphospholipid syndrome), advanced age, patients with prolonged periods of immobilisation, malignancies, contraceptives and hormone replacement therapy, surgery/trauma, obesity and smoking. Progression of existing Myelodysplastic Syndromes (MDS): A positive benefit/risk for romiplostim is only established for the treatment of thrombocytopenia associated with chronic ITP and romiplostim must not be used in other clinical conditions associated with thrombocytopenia. **PREGNANCY AND LACTATION:** **Pregnancy:** There are no or limited amount of data from the use of romiplostim in pregnant women. Lactation: It is unknown whether romiplostim/metabolites are excreted in human milk. **ADVERSE EFFECTS:** The most common adverse reactions observed include hypersensitivity reactions (including cases of rash, urticaria and angioedema) and headache. In an Indian phase III clinical study in patients with chronic immune thrombocytopenia (ITP), the most common ($\geq 5\%$) adverse events following administration of similar biologic romiplostim were upper respiratory tract infection (25.6%), pyrexia (15.4%), headache (12.8%), pruritus (10.3%), anaemia (7.7%), pain in extremity (7.7%), menorrhagia (7.7%), ecchymosis (7.7%), abdominal pain upper (5.1%), constipation (5.1%), diarrhoea (5.1%), gastritis (5.1%), vomiting (5.1%), chills (5.1%), non-cardiac chest pain (5.1%), pain in jaw (5.1%), acne (5.1%), dry skin (5.1%), petechiae (5.1%). **Kindly refer to full prescribing information on Romiset before prescribing. For further information, please contact:** Medical Affairs: Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra: 400 013. Prepared: 03rd August 2021, Source: Romiset Prescribing Information dated 1st July 2021.

For the treatment of HER2 +Ve breast cancer
& HER2 +Ve metastatic gastric cancer

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COMPOSITION: 150 mg and 440 mg multi-dose vials containing lyophilized powder for concentrate for solution for intravenous infusion. Reconstituted Hersima concentrate contains 21 mg/mL of trastuzumab, a humanised IgG1 monoclonal antibody expressed in Chinese hamster ovary cells. **INDICATION:** Treatment of HER2-overexpressing breast cancer. Treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. **CONTRAINDICATIONS:** Hersima is contraindicated in patients with known hypersensitivity to trastuzumab or to any other component of the product. **UNDESIRABLE EFFECTS:** **Adjuvant Breast Cancer** • Most common adverse reactions ($\geq 5\%$) are headache, diarrhea, nausea, and chills. **Metastatic Breast Cancer** • Most common adverse reactions ($\geq 10\%$) are fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash. **Metastatic Gastric Cancer** • Most common adverse reactions ($\geq 10\%$) are neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE Cardiomypathy:** HERSIMA can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue HERSIMA for cardiomyopathy. **Infusion Reactions:** Discontinue HERSIMA for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. **Embryo-Fetal Toxicity:** Exposure to HERSIMA during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception. **DOSAGE AND METHOD OF ADMINISTRATION:** HER2 testing is mandatory prior to initiation of HERSIM therapy. It should be administered as intravenous infusion. Do not administer as an intravenous push or bolus. **Weekly schedule:** **Loading dose:** The recommended initial loading dose is 4 mg/kg body weight. HERSIMA is administered as a 90-minute intravenous infusion. Subsequent doses: The recommended weekly dose of HERSIMA is 2 mg/kg body weight. If the prior dose was well tolerated, the dose can be administered as a 30-minute infusion. 3-weekly schedule initial loading dose of 8 mg/kg 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. If the prior dose was well tolerated, the dose can be administered as a 30-minute infusion. Reconstituted Hersima should be diluted in 250 mL of normal saline for infusion. Duration of therapy 52 weeks in patients with HER2 overexpressing adjuvant breast cancer. T11 disease progression in patients with HER2 overexpressing metastatic breast and metastatic gastric cancer. **SHELF-LIFE OF THE RECONSTITUTED SOLUTION** 440 mg/150 mg Reconstituted solutions made with bacteriostatic water for injection for 440 mg/150 mg vials of trastuzumab, as supplied, are stable for 28 days when refrigerated at 2°C to 8°C. Shelf-life of the solution for infusion containing the reconstituted product The infusion solution (0.9% sodium chloride infusion solution) containing the reconstituted product is physically and chemically stable for 24 hours (do not store above 30°C). **NATURE AND CONTENTS OF CONTAINER** HERSIMA™ finished product 150 mg lyophilized sterile powder under vacuum in glass vial, provided with bacteriostatic water for injection for reconstitution. HERSIMA™ finished product 440 mg lyophilized sterile powder under vacuum in glass vial, provided with bacteriostatic water for injection for reconstitution. For Further Information, Contact Details: Medical Affairs; Alkem House; Senapati Bapat Marg, Lower Parel; Mumbai, Maharashtra: 400 013.



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GCRI



Dr. Shalabh Arora,
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Dr. N. Thejeswar
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Dr. Sherry Abraham,
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