INDIAN SOCIETY OF MEDICAL & PAEDIATRIC ONCOLOGY

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

Scientific Committee Chair

Dr. Kumar Prabhash

Dr. Manju Sengar

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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

Organizing Secretary

Dr. B.K. Smruti
Dr. Jyoti Bajpai

Scientific Committee Chair

Dr. Kumar Prabhash
Dr. Manju Sengar

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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 Leighl
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 Warrier, 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 Disscusant: 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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Scientific Program | Day 4 | 28th January 2022

Time	Topic
	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 metastsis 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 1st 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 Warrier, 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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Scientific Program | Day 5 | 29th January 2022

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. Warrier, 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 Chabbra
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 Disscusant: 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 stratgeies on metastatic Bladder cancer : putting chemotherapy on the backburner Speaker: Dr. Bharat Vaswani

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Scientific Program | Day 5 | 29th January 2022

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 Tommorrow** 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. Bhausaheb 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. Rajeev Vijayakumar, Dr. Prashant Mehta, Dr. Prakash N.P
12:35 - 12:40	Vote of thanks

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- In combination with an aromatase inhibitor
- In combination with fulvestrant in women who have received prior endocrine therapy
- In pre or perimenopausal women, the endocrine therapy should be combined with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist.[3]

For Men:

Palbociclib is 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:

- **An aromatase inhibitor as initial endocrine-based therapy**
- **Fulvestrant in patients who have received prior therapy**[3]

STRENGTH FROM...

- **Powerful clinical efficacy**[3-12]
- **Real-world experience**[13]
- **Patient-reported outcomes**[14-15]
- **Established safety profile**[3-5, 8-10, 12, 16, 17]
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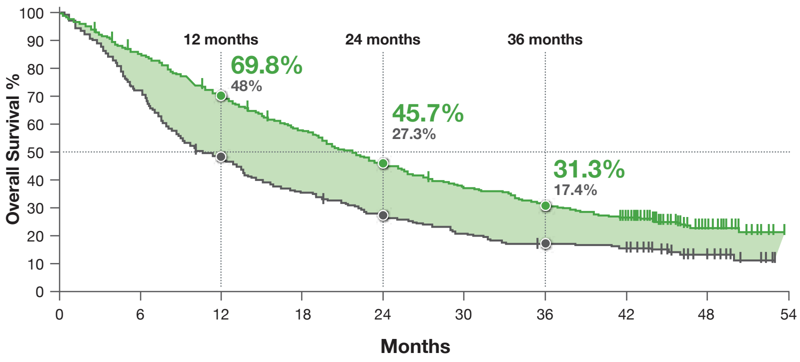


— Pembrolizumab + Chemotherapy — Placebo + Chemotherapy

	Median OS, mo (95% CI)[1]	Median PFS, mo (95% CI)[1]
Pembrolizumab + Chemotherapy	**22.0** (19.5 - 24.5)	**9.0** (8.1 - 10.4)
Placebo + Chemotherapy	10.6 (8.7 - 13.6)	4.9 (4.7 - 5.5)
HR	**0.60** (0.50 - 0.72)	**0.50** (0.41 - 0.59)

	Pembrolizumab + Chemotherapy n=405	Placebo + Chemotherapy n=202
Treatment Related, AEs, n (%)[1]	376 (92.8)	183 (90.6)

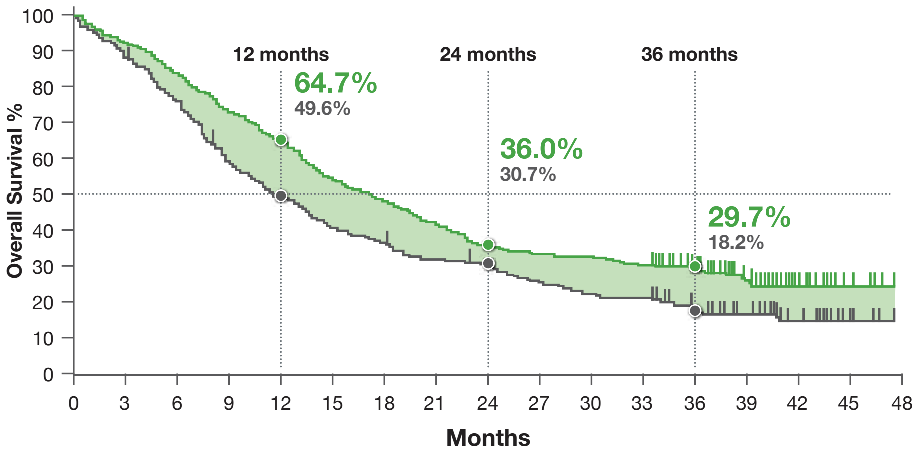
Median follow-up = 46.3 months (range: 41.8–54.1 months). Data cutoff: August 28, 2020. • #Patient with EGFR or ALK genomic tumor aberrations excluded. • 1. Gray et al. Presented at WCLC 2020. Abstract FP13.02. • 2. Rodríguez-Abreu et al., Annals of Oncology, Volume 32, Issue 7, July 2021, 881-895. • 3. Gandhi L, et al., Pembrolizumab plus Chemotherapy in Metastatic Non-Small-Cell Lung Cancer. N Engl J Med. 2018 May 31;378(22):2078-2092.

Study Design[3]:
Double-blind, phase 3 trial, with metastatic nonsquamous NSCLC without sensitizing EGFR or ALK mutations who had received no previous treatment for metastatic disease, ECOG PS of 0 or 1; had at least one measurable lesion according to RECIST 1.1; and had provided a tumor sample for determination of PD-L1 status. Patients were excluded if they had symptomatic CNS metastases, had a history of noninfectious pneumonitis that required the use of glucocorticoids, had active autoimmune disease, or were receiving systemic immunosuppressive treatment. Because of an increased risk of pneumonitis, patients were also excluded if they had received more than 30 Gy of radiotherapy to the lung in the previous 6 months. Patients were randomly assigned (in a 2:1 ratio, n=616) to receive investigator's choice of cisplatin (75 mg/m2 of BSA) or carboplatin (AUC 5 mg/ml/min) plus pemetrexed (500 mg/m2), all administered intravenously every 3 weeks, plus either 200 mg of pembrolizumab or placebo every 3 weeks for 4 cycles, followed by pembrolizumab or placebo for up to a total of 35 cycles plus pemetrexed maintenance therapy. Crossover to pembrolizumab monotherapy was permitted among the patients in the placebo-combination group who had verified disease progression. The primary end points were OS and PFS, as assessed by BICR. The secondary end points were the ORR, DOR and safety.

KEYTRUDA®
(pembrolizumab) Injection 100 mg

Keytruda plus chemotherapy demonstrates superior OS & PFS in 1st line Metastatic Squamous NSCLC patients#,1

KN407



— Pembrolizumab + Chemotherapy — Placebo + Chemotherapy

	Median OS, mo (95% CI)[1]	Median PFS, mo (95% CI)[1]
Pembrolizumab + Chemotherapy	**17.2** (14.4 - 19.7)	**8.0** (6.3 - 8.5)
Placebo + Chemotherapy	11.6 (10.1 - 13.7)	5.1 (4.3 - 6.0)
HR	**0.71** (0.59 - 0.86)	**0.59** (0.49 – 0.71)

	Pembrolizumab + Chemotherapy n=278	Placebo + Chemotherapy n=280
Treatment Related, AEs, n (%)[1]	274 (98.6)	275 (98.2)

Median Follow-up = 40.1 months (33.1-49.4 months) Data cutoff: September 30, 2020. • #Patient with EGFR or ALK genomic tumor aberrations excluded • 1. A Robinson ELCC 2021. Journal of Thoracic Oncology (2021) 16 (suppl_4): S748-S802. • 2. Paz-Ares L et al., Pembrolizumab plus Chemotherapy for Squamous Non-Small-Cell Lung Cancer. N Engl J Med. 2018 Nov 22;379(21):2040-2051.

Study Design[2]:
Phase 3, randomized, multicenter, double-blind, placebo-controlled trial in systemic treatment–naïve patients with metastatic squamous NSCLC, regardless of PD-L1 tumor expression status and ECOG PS 0 or 1. Patients with autoimmune disease that required systemic therapy within 2 years of treatment; a medical condition that required immunosuppression; or who had received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible. Patients were randomized to receive KEYTRUDA 200 mg Q3W, carboplatin Q3W, and either paclitaxel Q3W or nab-paclitaxel Q1W intravenously for four 3-week cycles followed by KEYTRUDA 200 mg Q3W (n=278); or placebo and carboplatin Q3W and either paclitaxel Q3W or nab-paclitaxel Q1W intravenously for four 3- week cycles followed by placebo Q3W (n=281). Treatment continued until progression of disease, unacceptable toxicity, or up to 24 months. The major efficacy outcome measures were PFS, ORR, OS. An additional efficacy outcome measure was DOR. PFS, ORR, and DOR were assessed by BICR per RECIST v1.1. Patients receiving carboplatin and either paclitaxel or nab-paclitaxel alone who experienced disease progression could cross over to receive KEYTRUDA as monotherapy.

Abridged Prescribing Information
KEYTRUDA®

[Pembrolizumab Injection 100mg/4mL (25mg/mL in a single vial)] **INDICATIONS:** KEYTRUDA® (pembrolizumab) is indicated: • For the treatment of patients with unresectable or metastatic melanoma.; • As monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express PD-L1 with a ≥50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations. • As monotherapy for the treatment of locally advanced or metastatic NSCLC in adults whose tumours express PD-L1 with a ≥1% TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving KEYTRUDA®. • In combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations. • In combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC. • For the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. • In combination with platinum and 5-fluorouracil (5-FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC). • As a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1]. **DOSE, METHOD OF ADMINISTRATION AND USAGE:** Posology & Methods of administration - Treatment must be initiated and supervised by specialist physicians experienced in the treatment of cancer. Patient Selection - For treatment of Non-Small Cell Lung Carcinoma as Monotherapy. Patients with NSCLC should be selected for treatment based on the tumour expression of PD-L1 confirmed by a validated test. KEYTRUDA® is administered as an intravenous infusion over 30 minutes every 3 weeks. Recommended Dosing - The recommended dose of KEYTRUDA® is: • Melanoma: 2 mg/kg every 3 weeks • NSCLC: 2 mg/kg every 3 weeks for second line patients, 200 mg every 3 weeks for first line monotherapy and combination therapy • HNSCC: 200 mg every 3 weeks • Urothelial Carcinoma: 200 mg every 3 weeks. **USE IN SPECIAL POPULATION:** Pregnancy - There are no data on the use of pembrolizumab in pregnant women. KEYTRUDA® is not recommended during pregnancy unless the clinical benefit outweighs the potential risk to the fetus. Women of childbearing potential should use effective contraception during treatment with KEYTRUDA® and for at least 4 months after the last dose of KEYTRUDA®. Nursing Mothers - It is unknown whether KEYTRUDA® is secreted in human milk. Pediatric Patients - Safety and efficacy of KEYTRUDA® in children below 18 years of age have not yet been established. Geriatric Patients - No overall differences in safety or efficacy were reported between elderly patients (65 years and over) and younger patients (less than 65 years). No dose adjustment is necessary in this population. Renal Impairment - No dose adjustment is needed for patients with mild or moderate renal impairment. KEYTRUDA® has not been studied in patients with severe renal impairment. Hepatic Impairment - No dose adjustment is needed for patients with mild hepatic impairment. KEYTRUDA® has not been studied in patients with moderate or severe hepatic impairment. **CONTRA- INDICATIONS:** None. **WARNING AND PRECAUTIONS:** Immune-mediated adverse reactions - In clinical trials, most immune-mediated adverse reactions were reversible and managed with interruptions of KEYTRUDA®, administration of corticosteroids and/or supportive care. Based on the severity of the adverse reaction, withhold KEYTRUDA® and consider administration of corticosteroids. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Restart KEYTRUDA® if the adverse reaction remains at Grade 1 or less following corticosteroid taper. If another episode of a severe adverse reaction occurs, permanently discontinue KEYTRUDA®. Immune-mediated pneumonitis - Pneumonitis (including fatal cases) has been reported in patients receiving KEYTRUDA®. Monitor patients for signs and symptoms of pneumonitis. If pneumonitis is suspected, evaluate with radiographic imaging and exclude other causes. Administer corticosteroids for Grade 2 or greater events (initial dose of 1-2 mg/kg/day prednisone or equivalent followed by a taper), withhold KEYTRUDA® for moderate (Grade 2) pneumonitis, and permanently discontinue KEYTRUDA® for severe (Grade 3), life- threatening (Grade 4) or recurrent moderate (Grade 2) pneumonitis. Immune-mediated colitis - Monitor patients for signs and symptoms of colitis and exclude other causes. Administer corticosteroids for Grade 2 or greater events (initial dose of 1-2 mg/kg/day prednisone or equivalent followed by a taper), withhold KEYTRUDA® for moderate (Grade 2) or severe (Grade 3) colitis, and permanently discontinue KEYTRUDA® for life- threatening (Grade 4) colitis. Immune-mediated hepatitis - Monitor patients for changes in liver function (at the start of treatment, periodically during treatment and as indicated based on clinical evaluation) and symptoms of hepatitis and exclude other causes. Administer corticosteroids (initial dose of 0.5-1 mg/kg/day [for Grade 2 events] and 1-2 mg/kg/day [for Grade 3 or greater events] prednisone or equivalent followed by a taper) and based on severity of liver enzyme elevations, withhold (AST or ALT) >3 to 5 times upper limit of normal (ULN) or total bilirubin >1.5 to 3 times ULN) or permanently discontinue (AST or ALT >5 times ULN or total bilirubin >3 times ULN) KEYTRUDA®. Immune-mediated nephritis - Monitor patients for changes in renal function and exclude other causes. Administer corticosteroids for Grade 2 or greater events (initial dose of 1-2 mg/kg/day prednisone or equivalent followed by a taper), withhold KEYTRUDA® for moderate (Grade 2), and permanently discontinue KEYTRUDA® for severe (Grade 3) or life-threatening (Grade 4) nephritis. Immune-mediated endocrinopathies - Adrenal insufficiency (primary and secondary) has been reported in patients receiving KEYTRUDA®. Hypophysitis has also been reported in patients receiving KEYTRUDA®. Monitor patients for signs and symptoms of adrenal insufficiency and hypophysitis (including hypopituitarism) and exclude other causes. Administer corticosteroids to treat adrenal insufficiency and other hormone replacement as clinically indicated, withhold KEYTRUDA® for moderate (Grade 2), withhold or discontinue KEYTRUDA® for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency or hypophysitis. Type 1 diabetes mellitus, including diabetic ketoacidosis, has been reported in patients receiving KEYTRUDA®. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Administer insulin for type 1 diabetes and withhold KEYTRUDA® in cases of severe hyperglycemia until metabolic control is achieved. Thyroid disorders, including hyperthyroidism, hypothyroidism and thyroiditis have been reported in patients receiving KEYTRUDA® and can occur at any time during treatment; therefore, monitor patients for changes in thyroid function (at the start of treatment, periodically during treatment and as indicated based on clinical evaluation) and clinical signs and symptoms of thyroid disorders. Hypothyroidism may be managed with replacement therapy without treatment interruption and without corticosteroids. Hyperthyroidism may be managed symptomatically. Withhold or discontinue KEYTRUDA® for severe (Grade 3) or life- threatening (Grade 4) hyperthyroidism. For patients with severe (Grade 3) or life- threatening (Grade 4) endocrinopathy that improves to Grade 2 or lower and is controlled with hormone replacement, continuation of KEYTRUDA® may be considered. Severe skin reactions - Monitor patients for suspected severe skin reactions and exclude other causes. Based on the severity of the adverse reaction, withhold or permanently discontinue KEYTRUDA® and administer corticosteroids. Cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some with fatal outcome, have been reported in patients treated with KEYTRUDA®. For signs or symptoms of SJS or TEN, withhold KEYTRUDA® and refer the patient for specialized care for assessment and treatment. If SJS or TEN is confirmed, permanently discontinue KEYTRUDA®. Other immune-mediated adverse reactions Permanently discontinue KEYTRUDA® for severe or life-threatening (Grade 3 or 4) myocarditis, encephalitis, or Guillain-Barré syndrome. Acute graft-versus-host-disease (GVHD), including fatal GVHD, after treatment with KEYTRUDA has been reported in patients. Transplant-related adverse reactions with a history of allogeneic hematopoietic stem cell transplant (HSCT). Patients who experienced GVHD after their transplant procedure may be at increased risk for GVHD after treatment with KEYTRUDA. Consider the benefit of treatment with KEYTRUDA versus the risk of possible GVHD in patients with a history of allogeneic HSCT. Infusion- related reactions - Severe infusion reactions, including hypersensitivity and anaphylaxis, have been reported in 6 (0.2%) of 2799 patients receiving KEYTRUDA® in KEYNOTE- 001, KEYNOTE-002, KEYNOTE-006 and KEYNOTE-010. For severe infusion reactions, stop infusion and permanently discontinue KEYTRUDA®. Patients with mild or moderate infusion reaction may continue to receive KEYTRUDA® with close monitoring; premedication with antipyretic and antihistamine may be considered. **UNDESIRABLE SIDE-EFFECTS:** Treatment-related serious adverse events (SAEs) reported up to 90 days after the last dose occurred in 10% of patients receiving KEYTRUDA®. Of these treatment-related SAEs, the most common were pneumonitis, colitis, diarrhea, and pyrexia. Transplant-related adverse reactions: Solid organ transplant rejection has been reported in the post-marketing setting in patients treated with KEYTRUDA®. Treatment with KEYTRUDA® may increase the risk of rejection in solid organ transplant recipients. Consider the benefit of treatment with KEYTRUDA® versus the risk of possible organ rejection in these patients. Other adverse events: The adverse events that occurred in at least 10% of patients with melanoma treated with KEYTRUDA® in KEYNOTE-006 i.e. Arthralgia (18%), Back pain (12%), Cough (17%), Vitiligo (11%). Also, the adverse events that occurred in at least 10% of patients with melanoma treated with KEYTRUDA® at a dose of 2mg/kg in KEYNOTE-002 i.e. Abdominal pain (13%), Pruritus (25%), Rash (13%), Hyponatremia (11%), Arthralgia (15%). Post-marketing Experience: The following adverse reactions have been identified during post-approval use of KEYTRUDA®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Immune system disorders: hemophagocytic lymphohistiocytosis. **For complete undesirable side effects, please refer to the full prescribing information. PRESENTATION:** Each carton contains one 100 mg/4 mL (25 mg/mL), single-use vial. **STORAGE CONDITIONS:** Store in a refrigerator (2°C to 8°C). Protect from light. Do not freeze. Do not shake. Storage conditions after dilution: The diluted product should be used immediately. If not used immediately, diluted solutions of KEYTRUDA® may be stored at room temperature for a cumulative time of up to 6 hours. Diluted solutions of KEYTRUDA® may also be stored under refrigeration at 2°C to 8°C; however, the total time from dilution of KEYTRUDA® to completion of infusion should not exceed 96 hours. If refrigerated, allow the vials and/or IV bags to come to room temperature prior to use. Translucent to white proteinaceous particles may be seen in the diluted solution. Shelf Life - 24 Months.

Current ABPI is based on PI version MSDIN 10/21

Before prescribing KEYTRUDA®, please consult the full prescribing information.

Mode of reporting the adverse event	Details
Fax	0124-4375562
Toll Free Number	18001032642
E-mail	pharmacovigilance.india@merck.com
Postal Address	lobal Pharmacovigilance Department, MSD Pharmaceuticals Pvt. Ltd., 6th Floor, Vatika Towers-B, Sector-54, Gurgaon- 122002.

Adverse Event (AE): Per the International Conference on Harmonization (ICH), an adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this product.

Privacy Note: Any personal data provided by you will be treated by MSD with full respect of your privacy. Please read more about MSD's privacy commitment at www.merck.com/privacy/. In case you want to delete or edit Personal Health Information (PHI) already collected by MSD India please request at by MSD Pharmacovigilance.india@merck.com or call at 1244652637"
Global Pharmacovigilance, MSD Pharmaceuticals Pvt Ltd.

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IN-KEY-00531 - 07/12/2021 - 07/12/2022

MSD

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durvalumab
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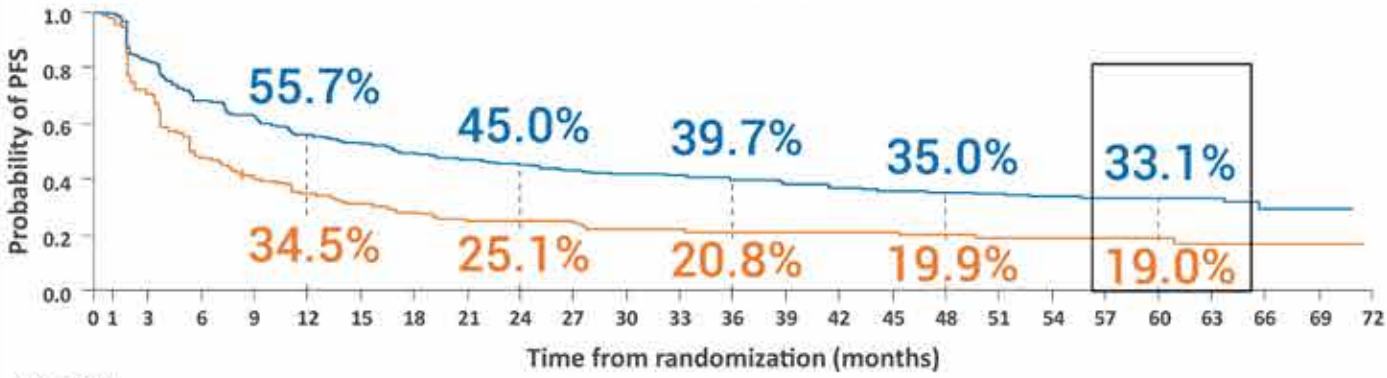
IMMUNOTHERAPY TO SHOW SUSTAINED AND DURABLE

PFS OF 33.1% BENEFIT AT 5 YEARS[1]

	No. of events / No. of patients (%)	Median PFS (95% CI) months
Durvalumab	268/476 (56.3)	16.9 (13.0–23.9)
Placebo	175/237 (73.8)	5.6 (4.8–7.7)

Stratified HR for progression or death (95% CI): 0.55 (0.45–0.68)



No. at risk

Durva.	476	377	301	267	215	190	165	147	137	128	119	110	103	97	92	85	81	78	67	57	34	22	11	5	0
Placebo	237	164	105	87	68	56	48	41	37	36	30	27	26	25	24	24	22	21	19	19	14	6	4	1	0

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DCO5: January 11, 2021; median follow-up: all patients, 34.2 months [range, 0.2–74.7]; censored patients, 61.6 months [range, 0.4–74.7].
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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42% reduced risk of death demonstrated with atezolizumab + bevacizumab vs sorafenib[1]

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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*1: Nuparp prescribing information *Price to Patient *Data on file*

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250mcg
500mcg

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 0.5 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). **INDICATION(S):** Romiplostim is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). **POSOLOGY 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 ≥ 50 x 109/L. Platelet counts should be assessed weekly until a stable platelet count (≥ 50 x 109/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:** Reoccurrence of thrombocytopenia and bleeding after cessation of treatment: Thrombocytopenia is likely to reoccur 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. ATIII 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 (≥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

Hersima

Trastuzumab inj 150 mg / 440 mg for IV use

Her Care!

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HERSIMA (Biosimilar Trastuzumab)

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 (≥5%) are headache, diarrhea, nausea, and chills. **Metastatic Breast Cancer •** Most common adverse reactions (≥ 10%) are fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash. **Metastatic Gastric Cancer •** Most common adverse reactions (≥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 Cardiomyopathy:** 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, Pulmonary Toxicity: 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 administrated 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 Till 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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