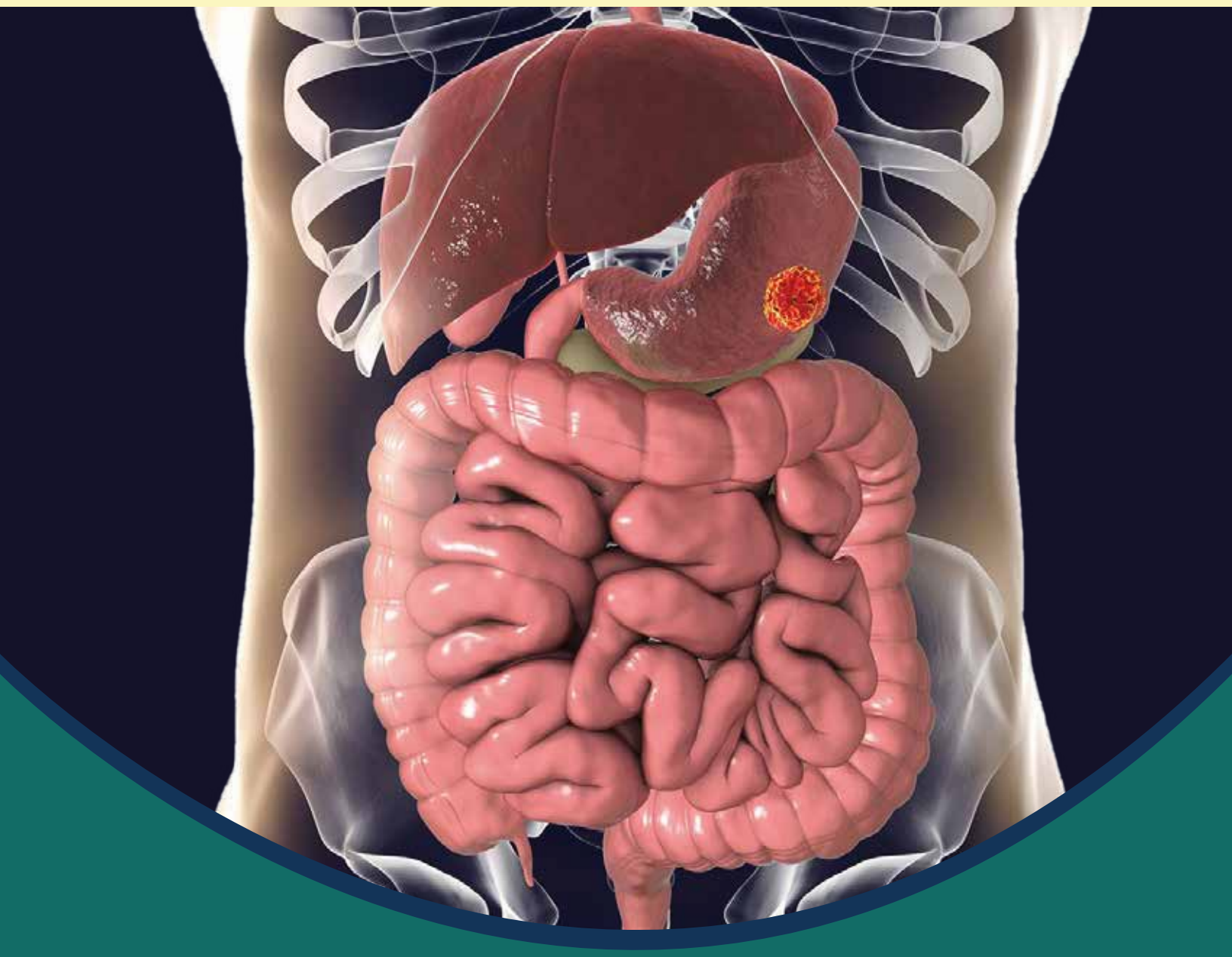
5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS



Virtual Meet

22nd -24th JULY 2022

ORGANISING TEAM

Dr. Anil Heroor
Director Surgical Oncology,
Fortis Hospital,
Mumbai

Dr. Tejinder Singh
Sr. Consultant Medical Oncologist
Apollo Cancer Center,
Apollo Hospital, Mumbai

Dr. Adwaita Gore
Associate Director Medical Oncology
Nanavati Max Super Speciality,
Mumbai

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5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

22nd - 24th JULY 2022

Dear Colleagues,

GKCT brings to you the 5th Edition of Annual Review in Gastrointestinal Cancer to be held on 22nd-24th July 2022 on a Virtual Platform.

The primary goal of this meeting is to guide practicing physicians on integrating the best and most current evidence into day-to-day routine care for patients with GI cancers. This meeting brings a practical perspective on how to optimize multidisciplinary care for some of the more complex clinical management decisions. Topics discussed include locoregional modalities, the role of minimally invasive procedures, and state-of-the-art treatment.

As we are aware chemotherapy dependency has maintains its validity in several gastrointestinal cancers and continues to be successfully explored, especially in academic trials. However,a number of biomarkers currently guide treatment decisions for patients with gastrointestinal neoplasms.Major technological advances in genomics have made it possible to identify critical genetic alterations in cancer, rendering oncology well along the path to “personalized cancer medicine”.

Image-guided surgery & minimally invasive treatment has evolved over the past several decades, which has led to reduced local recurrence rates and improved survival outcomes. The approach to diagnosis, staging, and selection of appropriate treatment modalities has become a multidisciplinary effort combining interventional endoscopy, surgery, and radiology tools needs to be discussed and implemented in our practice.

This meeting focuses on case-based and didactic presentations from national international experts in the treatment of the whole spectrum of gastrointestinal (GI) cancers, including esophageal, gastric, hepatocellular, pancreatic, small bowel, bile duct, anal and colorectal, and gallbladder. Our year in review session, hall mark surgical video sessions and case based panel discussion will provide an overview of exciting new research in the area of gastrointestinal tumours that may establish the stage for an innovative personalized management and precision medicine modalities for individualized care.

We are sure our attempt in understanding the various therapeutic interventions will pave the way for improved patient outcomes. We look forward to your active participation.

Regards

Dr. Anil Heroor
Director Surgical Oncology,
Fortis Hospital,
Mumbai

Dr. Tejinder Singh
Sr. Consultant Medical Oncologist
Apollo Cancer Center,
Apollo Hospital, Mumbai

Dr. Adwaita Gore
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MEETING HIGHLIGHTS

- Surgical Master Video Session
- Year in Review in GI Cancer Session
- Molecular Tumor Board and Case Based Panel Discussion
- Eminent Speaker Sessions (Surgical and Medical)
- Molecular Oncology Session

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5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

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Day 1 | 22nd July 2022 Scientific Program

Industry Symposium

6.00pm – 6.30pm	**Sponsored by Bristol Myers Squibb** Immune checkpoint inhibitors in 1L Gastric Cancer, GEJC and EAC **Speaker: Dr. Tejinder Singh**
6.30pm – 7.00pm	**Sponsored by Intas** Role of S1 in GI management in Indian Scenario **Speaker: Dr. Prabhat Bhargava**
7.00pm – 7.30pm	**Sponsored by AstraZeneca** Newer Avenues in Management of Advanced BTC **Speaker: Dr. B.K. Smruti**
7.30pm – 8.00pm	**Sponsored by Lilly** Reecent Advances in the Management of Second Line Gastric Cancer **Speaker: Dr. Ashish Singh**
8.00pm – 8.30pm	**Sponsored by Roche** Panel Discussion on Treatment Strategies with Atezolizumab & Bevacizumab in Unresectable HCC **Moderator: Dr. Bhushan Nemade** **Panelists –** **Dr. Tejinder Singh** **Dr. Preetam Jain** **Dr. Aditya Kale** **Dr Amit Mandot** **Dr. Rahul Sheth**

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Day 2 | 23rd July 2022 Scientific Program

Session 1 : Esophagus/Stomach Cancers

6:00pm – 6:10pm	**Chairpersons -** **Dr. Shirish Alurkar** **Dr. Girish Phadke** Updates in Surgical Management of Localized EG Cancers **Speaker: Dr. M. Satish Kumar**
6:10pm – 6:20pm	Management of Metastatic EG Cancer **Speaker: Dr. Pritam Kalaskar**
6:20pm – 6:40pm	Should all Patients with EG Cancer Receive Immunotherapy? **Yes – Dr. M. Vamshi Krishna** **No – Dr. Peush Bajpai** **Debate Moderator :** **Dr. Bharat Bhosale**
6:40pm – 7:10pm	**Chairpersons -** **Dr. Satish Midha** **Dr. Atul Sharma** **Panel Discussion:** Practice Changing Papers in Esophageal / Gastric Cancers **Moderator: Dr. Vedant Kabra** **Panelists:** **Dr. Rajesh Shinde** **Dr. Rudraprasad Acharya** **Dr. Gajanan Kanitkar** **Dr. Atul Narayankar** **Dr. Sandeep De** **Dr. Indranil Mallick** **Dr. Nikhil Kalyani** **Dr. Nilesh Lokeshwar** **Dr. Nikhil Gulavani** **Dr. Mukurdipi Ray**

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Day 2 | 23rd July 2022 Scientific Program

Session 2 : Pancreatic Cancer

7:10pm – 7:35pm	**Chairpersons -** **Dr. D. C. Doval** **Dr. Abhijit Talukdar** **Debate :** Borderline Resectable Pancreatic Cancer **To Radiate : Dr. Manish Chandra** **Not To Radiate: Dr. Shaikat Gupta** **Debate Moderator:** **Dr. Adarsh Chaudhary**
7:35 – 7:50pm	Advances in the Systemic Treatment of Pancreatic Cancer **Speaker: Dr. Niti Raizada**
7:50pm – 8:20pm	**Chairpersons -** **Dr. Sanjay Sonar** **Dr. Shefali Agrawal** **Panel Discussion:** Practice Changing Papers in Pancreatic Cancers **Moderator: Dr. Chetan Kantharia** **Panelists:** **Dr. Rajat Bhargava** **Dr. Caleb Harris** **Dr. Ramakrishnan A.S.** **Dr. Deepanjali Adulkar** **Dr. Upasna Saxena** **Dr. Amol Dongre** **Dr. Krishnakumar Rathnam** **Dr. Sujai Hegde**

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Day 2 | 23rd July 2022 Scientific Program

Session 3 : Hepatocellular Carcinoma / Ca Gall Bladder

8:20pm – 8:45pm	**Chairpersons -** **Dr. S. H. Advani** **Dr. Naresh Somani** Debate : Integrating Immunotherapy Into Earlier-Stage HCC **Yes – Dr. Pritam Kataria** **Not Yet - Dr. Ravi Jaiswal** **Debate Moderator:** **Adwaita Gore**
8:45pm – 9:00pm	Leaping the Boundaries of Liver Cancer Surgery **Speaker: Dr. Ganesh Nagrajan**
9:00pm – 9:30pm	**Chairpersons -** **Dr. Vivek Agarwala** **Dr. Shishir Shetty** **Panel Discussion:** Practice Changing Papers in HCC/Gall Bladder **Moderator: Dr. Vineet Talwar** **Panelists:** **Dr. Shraddha Patkar** **Dr. Aniruddha Kulkarni** **Dr. Nikhil Pande** **Dr. Chandrakanth M.V.** **Dr. Suhas Aagre** **Dr. Sandeep Bhoriwal** **Dr. Shailesh Bondarde** **Dr. Chandrashekhar Pethe**

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Day 3 | 24th July 2022 Scientific Program

Session 4 : Colorectal Cancers

6:00pm – 6:10pm	**Chairpersons -** **Dr. K Pavithran** **Dr. Mehul Bhansali** Tailoring Treatment for Early-Stage CRC **Speaker: Dr. Avanish Saklani**
6:10pm – 6:35pm	**Debate:** What's the Best Sequence of Therapy for Locally Advanced Rectal? Radiation First : **Dr. Reena Engineer** Chemotherapy First : **Dr. Chetan Deshmukh**
6:35pm – 6:45pm	Finding the Optimal Window for Anti-EGFR Treatment **Speaker: Dr. Prasad Narayanan**
6:45pm – 6:55pm	New and Emerging Later-Line Therapies in Advanced CRC **Speaker: Dr. Rahul Kulkarni**
6:55pm – 7:20pm	**Chairpersons -** **Dr. Rajeev Joshi** **Dr. Avinash Supe** **Debate:** Quadruple or Triple Therapy in First-Line Advanced CRC Quadruple Therapy : **Dr. Bhuvan Chugh** Triplet Therapy **Dr. Prabhat Bhargava** **Moderator: Dr. Manish Kumar**

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Day 3 | 24th July 2022 Scientific Program

Session 4 : Colorectal Cancers

7:20pm – 7:50pm	**Panel discussion:** Practice Changing Abstracts in CRC **Moderator: Dr. Nitesh Rohatgi** **Panelists:** **Dr. Wesley Jose** **Dr. Nirmal Raut** **Dr. Smita Kayal** **Dr. Ashwin Desouza** **Dr. Deep Goel** **Dr. Sandeep Nayak** **Dr. Poornima Subrahmanya**
7:50pm – 8:50pm	**Chairpersons -** **Dr. Anuradha Chougule** **Dr. P. K. Julka** Molecular Tumour Board **Moderator: Dr. T. Raja** **Panelists:** **Dr. Amit Rauthan** **Dr. B. K. Smruti** **Dr. Suparna Rao** **Dr. Tejinder Singh** **Dr. Uma Dangi** **Dr. Bharat Bhosale**
8:50pm – 9:00pm	Vote of Thanks

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OPDYTA® (nivolumab) + YERVOI® (ipilimumab)

Durable, long-term survival now possible across tumours*

1L aRCC

OPDYTA®, in combination with YERVOI®, is indicated for the treatment of patients with intermediate or poor risk, previously untreated advanced RCC.

NEW 1L mNSCLC

OPDYTA®, in combination with YERVOI®, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

OPDYTA®, in combination with YERVOI® & 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

Dual I-O therapy now approved & available in India

Abridged Prescribing Information (API)

To be sold by retail on the prescription of a Registered Oncologist only YERVOI® 5 mg/mL concentrate for solution for infusion.**Composition**: One vial of 10 mL contains 50mg of Ipilimumab. **Therapeutic Indications:** Renal Cell Carcinoma (RCC) Ipilimumab is indicated for treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with nivolumab. **Non-Small Cell Lung Cancer (NSCLC)** Ipilimumab, in combination with nivolumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. Ipilimumab, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations. **Dosage and administration:** RCC Combination phase: The recommended dose during the combination phase is ipilimumab 1 mg/kg administered intravenously over a period of 30 minutes every 3 weeks for the first 4 doses in combination with nivolumab 3 mg/kg administered intravenously over a period of 30 minutes, followed by the single-agent phase. Single-agent phase: The recommended dose of nivolumab during the single-agent phase is 3 mg/kg every 2 weeks administered intravenously over a period of 30 minutes. When administered in combination with nivolumab, nivolumab should be given first followed by ipilimumab on the same day. **NSCLC** The recommended dose of ipilimumab in combination with nivolumab is nivolumab 3 mg/kg administered as an intravenous infusion over 30 minutes every 2 weeks and ipilimumab 1 mg/kg administered as an intravenous infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or for up to 2 years in patients without disease progression. The recommended dose of ipilimumab in combination with nivolumab and platinum-doublet chemotherapy is nivolumab 360 mg administered as an intravenous infusion over 30 minutes every 3 weeks and ipilimumab 1 mg/kg administered as an intravenous infusion over 30 minutes every 6 weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression. **Contraindications:** None. **Warnings and Precautions: Immune-related pneumonitis:** For Grade 3 or 4 pneumonitis, ipilimumab in combination with nivolumab must be permanently discontinued. For Grade 2 (symptomatic) pneumonitis, ipilimumab in combination with nivolumab should be withheld. **Immune-related colitis:** For Grade 3 & 4 diarrhea or colitis, ipilimumab in combination with nivolumab must be permanently discontinued. For Grade 2 diarrhea or colitis, ipilimumab in combination with nivolumab should be withheld. **Immune-related hepatitis:** Monitor for change in liver function. For Grade 3 or 4 transaminase or total bilirubin elevation, ipilimumab in combination with nivolumab must be permanently discontinued. For Grade 2 transaminase or total bilirubin elevation, ipilimumab in combination with nivolumab should be withheld. **Immune-related nephritis and renal dysfunction:** Monitor for changes in renal function.For Grade 4 serum creatinine elevation, ipilimumab in combination with nivolumab must be permanently discontinued. For Grade 2 or 3 serum creatinine elevation, ipilimumab in combination with nivolumab should be withheld. **Immune-related endocrinopathies:** Monitor for changes in thyroid function. For symptomatic hypothyroidism, ipilimumab in combination with nivolumab should be withheld, and thyroid hormone replacement should be initiated as needed. For symptomatic hyperthyroidism, ipilimumab in combination with nivolumab should be withheld. Ipilimumab in combination with nivolumab must be permanently discontinued for life-threatening (Grade 4) hyperthyroidism or hypothyroidism. For symptomatic Grade 2 adrenal insufficiency, ipilimumab in combination with nivolumab should be withheld. Ipilimumab in combination with nivolumab must be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. For symptomatic Grade 2 or 3 hypophysitis, Ipilimumab in combination with nivolumab should be withheld. Ipilimumab in combination with nivolumab must be permanently discontinued for life-threatening (Grade 4) hypophysitis. For symptomatic diabetes, ipilimumab in combination with nivolumab should be withheld. Ipilimumab in combination with nivolumab must be permanently discontinued for life-threatening (Grade 4) diabetes. **Immune-related skin adverse reactions:** Ipilimumab in combination with nivolumab should be withheld for Grade 3 rash and discontinued for Grade 4 rash. If symptoms or signs of Stevens- Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) appear, ipilimumab in combination with nivolumab should be withheld. If the patient has confirmed SJS or TEN, permanent discontinuation of ipilimumab in combination with nivolumab is recommended. **Other immune-related adverse reactions:** Ipilimumab in combination with nivolumab should be withheld for grade 3 (first occurrence) & should be permanently discontinued for Grade 4 or recurrent Grade 3 adverse reactions. Persistent Grade 2 or 3 adverse reactions despite management, inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day. For grade 3 myocarditis, nivolumab or nivolumab in combination with ipilimumab therapy should be permanently discontinued. Fatal or serious graft versus-host disease (GVHD) can occur in patients who receive a CTLA-4 receptor blocking antibody either before or after allogeneic hematopoietic stem cell transplantation (HSCT). Follow patients closely for evidence of GVHD and intervene promptly. **Infusion reaction:**In case of a severe or life-threatening infusion reaction, ipilimumab in combination with nivolumab infusion must be discontinued. Patients with mild or moderate infusion reaction may receive ipilimumab in combination with nivolumab with close monitoring and use of premedication according to local treatment guidelines for prophylaxis of infusion reactions. **Drug Interactions:** Ipilimumab is a human monoclonal antibody that is not metabolized by cytochrome P450 enzymes (CYPs) or other drug metabolizing enzymes.Other forms of interaction **Corticosteroids** The use of systemic corticosteroids at baseline, before starting ipilimumab, should be avoided. However, systemic corticosteroids or other immunosuppressant can be used after starting ipilimumab to treat immune-related adverse reactions. **Anticoagulants** The use of anticoagulants is known to increase the risk of gastrointestinal hemorrhage. Since gastrointestinal hemorrhage is an adverse reaction with ipilimumab, patients who require concomitant anticoagulant therapy should be monitored closely. **Pregnancy:** Ipilimumab is not recommended during pregnancy or in women of childbearing potential not using effective contraception, unless the clinical benefit outweighs the potential risk. **Nursing Mothers:** Discontinue breastfeeding. **Pediatric Use:** The safety and efficacy have not been established. **Geriatric Use:** No overall differences in safety or efficacy were reported between elderly (≥65 years) and younger patients (<65 years). **Hepatic Impairment:** Administer with caution in patients with transaminase levels 5 times ULN or greater, or bilirubin levels greater than 3 times ULN at baseline **Renal Impairment:** No specific dose adjustment is necessary in patients with mild to moderate renal impairment. **Adverse Reactions:** Fatigue, rash, pruritus, diarrhea, nausea, hypothyroidism, musculoskeletal pain, arthralgia, decreased appetite, pyrexia, vomiting and hyperthyroidism. Ipilimumab is associated with immune-related adverse reactions. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of ipilimumab. **Overdose:** Closely monitor for signs and symptoms of adverse reactions and appropriate symptomatic treatment should be instituted. **Storage:** Store in a refrigerator (2°C-8°C). Do not freeze. API based on prescribing information version 03.1, dated 11 May 2021 Issued – 02 July 2021 Before prescribing, consult full prescribing information. For further information, please contact: Bristol-Myers Squibb India Private Limited, 6th floor, Tower 1, One International Center, S.B. Marg, Elphinstone (W), Mumbai - 400 013, Tel: + 91 22 6628 8600.

*Claim applies to CM 227 & CM 214

aRCC: Advanced renal cell carcinoma, 1L: First-line, NSCLC: Non-small cell lung cancer | EGFR: Epidermal growth factor receptor; ALK: Anaplastic lymphoma kinase | Reference: 1. YERVOI® Prescribing Information (PI) dated 11 May 2021 (versions 3.1)

Bristol Myers Squibb™ | Bristol-Myers Squibb India Pvt. Ltd.
One International Center, 6th Floor, Tower 1, Senapati Bapat Marg, Elphistone (W), Mumbai- 400013

7356-IN-2100083 expiry 15 Sep 2022

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1L : 1st Line HCC : Hepatocellular Carcinoma mHCC : metastatic Hepatocellular Carcinoma

1. Finn RS, Qin S, Ikeda M, et al; IMbrave150 Investigators. Atezolizumab plus bevacizumab in unresectable hepatocellular carcinoma.N Engl J Med. 2020;382:1894-1905.

ABRIDGED PRESCRIBING INFORMATION (Tecentriq®) SUMMARY OF PRESCRIBING INFORMATION:

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

Generic Name: Atezolizumab Injection Brand Name: Tecentriq® Composition: Active ingredient: Atezolizumab. Tecentriq is supplied as a single-use vial containing preservative-free, colorless to slightly yellow solution, at an active ingredient concentration of 60 mg/mL as follows: 14 mL vial containing a total of 840 mg atezolizumab 20 mL vial containing a total of 1200 mg atezolizumab Indications: Tecentriq® is indicated for: Urothelial carcinoma (UC) Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma after prior chemotherapy or who are considered cisplatin ineligible. Non-small cell lung cancer. 1.Tecentriq is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. 2. Tecentriq in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies. 3. Atezolizumab in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. 4. Atezolizumab as monotherapy for the first line treatment of patients of metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells or > 10% tumor infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations. Small cell lung cancer: Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). Triple-negative breast cancer: Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumor have PD-L1 expression 1%, and who have not received prior chemotherapy for metastatic disease. Hepatocellular carcinoma: Atezolizumab, in combination with Bevacizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. Type of dosage form: Tecentriq® is available in single use vials as Concentrate for solution for infusion. Dosage and Administration: Tecentriq must be administered as an intravenous infusion under the supervision of a qualified healthcare professional. Do not administer as an IV push or bolus. The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes. The recommended dose of Tecentriq in monotherapy or combination therapy: 840 mg administered by IV infusion every 2 weeks, or 1200 mg administered by IV infusion every 3 weeks. Tecentriq monotherapy 2L NSCLC, 1L NSCLC, 2L UC & 1L UC in Cisplatin ineligible patients. Tecentriq combination therapy 1L non-squamous NSCLC: Tecentriq in combination with bevacizumab, paclitaxel, and carboplatin: During the induction phase, Tecentriq is administered according to its dosing schedules by intravenous (IV) infusion and bevacizumab, paclitaxel and carboplatin are administered every 3 weeks for four or six cycles. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion and bevacizumab is administered every 3 weeks. Tecentriq in combination with nab-paclitaxel and carboplatin: During the induction phase, the recommended dose of Tecentriq is 1200 mg administered by IV infusion, followed by nab-paclitaxel and carboplatin every 3 weeks for four or six cycles. For each 21-day cycle, Tecentriq, nab-paclitaxel and carboplatin is administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15. The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq is administered by IV infusion every 3 weeks. 1L ES-SCLC: Tecentriq in combination with carboplatin and etoposide: During the induction phase, Tecentriq is administered according to its dosing schedules by IV infusion and carboplatin and etoposide are administered by IV infusion every three weeks for four cycles. Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3. The induction phase is followed by a maintenance phase without chemotherapy in which Tecentriq is administered according to its dosing schedules by IV infusion. 1L TNBC: Tecentriq in combination with nab-paclitaxel:The recommended dose of Tecentriq is 840 mg administered by IV infusion, followed by 100 mg/m2 nab-paclitaxel. For each 28-day cycle Tecentriq is administered on days 1 and 15, and nab-paclitaxel is administered on days 1, 8 and 15 HCC: Tecentriq in combination with bevacizumab: Tecentriq is administered according to its dosing schedules by IV infusion, and bevacizumab 15 mg/kg is administered every 3 weeks. Duration of Treatment: Patients are treated with Tecentriq until disease progression or unacceptable toxicity in UC, NSCLC & ES-SCLC and patients are treated until disease progression or unacceptable toxicity in 1L TNBC. Contraindications: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. Warnings and Precautions: Immune-mediated pneumonitis: Cases of pneumonitis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 pneumonitis. Immune-mediated hepatitis: Cases of hepatitis, some leading to fatal outcomes, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or Grade 4 events. Immune-mediated colitis: Cases of diarrhea or colitis have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4 diarrhea or colitis. Immune-mediated endocrinopathies: Hypothyroidism, hyperthyroidism, adrenal insufficiency and type 1 diabetes mellitus, including diabetic ketoacidosis, have been observed in clinical trials with Tecentriq. For Grade 4 Hypophysitis, treatment with Tecentriq should be permanently discontinued. Immune-mediated meningoencephalitis: Meningoencephalitis has been observed in clinical trials with Tecentriq. Permanently discontinue for all grades of meningoencephalitis. Immune-mediated neuropathies: Myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome, which may be life threatening, were observed in patients receiving Tecentriq. Permanently discontinue Tecentriq for all grades of immune mediated neuropathies. Immune-mediated pancreatitis: Pancreatitis, including increases in serum amylase and lipase levels, has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 4, or any grade of recurrent pancreatitis. Immune-mediated myocarditis: Myocarditis has been observed in clinical trials with Tecentriq. Tecentriq should permanently discontinued for Grade 2 or above myocarditis. Myocarditis may also be a clinical manifestation of myositis and should be managed accordingly. Immune-mediated myositis: Cases of myositis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 recurrent myositis or Grade 4 events. Patients with possible myositis should be monitored for signs of myocarditis. Immune-mediated nephritis: Nephritis has been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 nephritis. Infusion related reactions: Infusion related reactions (IRRs) have been observed in clinical trials with Tecentriq. Tecentriq should be permanently discontinued in patients with Grade 3 or 4 infusion related reactions. Immune-mediated severe cutaneous adverse reactions: Immune-mediated severe cutaneous adverse reactions (SCARs), including cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients receiving Tecentriq. Patients should be monitored for suspected severe skin reactions and other causes should be excluded. Tecentriq should be permanently discontinued for Grade 4 skin reactions, and corticosteroids should be administered. For confirmed SJS or TEN, Tecentriq should be permanently discontinued. Special populations: Patients with autoimmune disease were excluded from clinical trials with Tecentriq. In the absence of data, Tecentriq should be used with caution in patients with autoimmune disease, after assessment of the potential risk-benefit. Embryofetal toxicity: Based on the mechanism of action, the use of Tecentriq may cause fetal harm. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related rejection of the developing fetus resulting in fetal death. Pregnant women should be advised of the potential risk to the fetus. Women of childbearing potential should be advised to use highly effective contraception during treatment with Tecentriq and for 5 months after the last dose. Disease Specific precautions: Use of Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin in metastatic non-squamous non-small cell lung cancer Physicians should carefully consider the combined risks of the four-drug regimen of atezolizumab bevacizumab, paclitaxel and carboplatin before initiating treatment. Use of atezolizumab in combination with nab-paclitaxel in metastatic triple negative breast cancer: Neutropenia and peripheral neutropathies occurring during treatment with atezolizumab and nabpaclitaxel may be reversible with interruptions of nab-paclitaxel. Physicians should consult the nab paclitaxel summary of product characteristics (SmPC) for specific precautions and contraindications of this medicine. Patients excluded from clinical trials: Patients with the following condition were excluded from clinical trials: a history of autoimmune disease, history of pneumonitis, active brain metastasis, HIV, hepatitis B or hepatitis C infection, significant cardiovascular disease and patients with inadequate hematologic and end-organ function. Patients who were administered a live, attenuated vaccine within 28 days prior to enrolment; systemic immune stimulatory agents within 4 weeks or systemic immunosuppressive medicinal products within 2 weeks prior to study entry were excluded from clinical trial. Use in Special population: Fertility: Based on animal studies, Tecentriq may impair fertility in females of reproductive potential while receiving treatment. Contraception: Female patients of childbearing potential should use highly effective contraception and take active measures to avoid pregnancy while undergoing Tecentriq treatment and for at least 5 months after the last dose. Pregnancy: There are no clinical studies of Tecentriq in pregnant women. Tecentriqis not recommended during pregnancy unless the potential benefit for the mother outweighs the potential risk to the fetus. Labor and Delivery: The use of Tecentriq during labor and delivery has not been established. Lactation: There is no information regarding the presence of atezolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. As human IgG is excreted in human milk, the potential for absorption and harm to the infant is unknown. Because of the potential for serious adverse reactions in breastfed infants from Tecentriq, advise women not to breastfeed during treatment and for at least 5 months after the last dose. Pediatric use: Tecentriq is not approved for use in patients under the age of 18 years. The safety and efficacy of Tecentriq in this population has not been established. Tecentriq did not demonstrate clinical benefit in pediatric patients in a clinical trial. Geriatric use: No overall differences in safety or efficacy were observed between patients 65 years of age and younger patients. Postmarketing Experience: Lung infection, Immunodeficiency, Blood sugar increased, chest infection, Pneumonitis, Platelet count low, Neutropenia, Hypothyroidism, Bedridden, Hip facture. Undesirable Effects: This is not the complete list. The very commonly reported Adverse Events (AEs) with Tecentriq in monotherapy includes fatigue, decreased appetite, cough, nausea, dyspnea, , diarrhea, pyrexia, vomiting, arthralgia, Musculoskeletal pain, back pain, urinary tract infection, asthenia, pruritus, rash, headache and in case of combination therapy it includes anemia, neutropenia, thrombocytopenia, leukopenia, hypothyroidism, constipation, peripheral oedema, lung infection, peripheral neuropathy, nasopharyngitis, alopecia, hypertension. No new adverse drug reactions have been identified from post marketing experience. Interactions with other medicinal products and other forms of interaction: No formal pharmacokinetic drug-drug interaction studies have been conducted with atezolizumab. Since atezolizumab is cleared from the circulation through catabolism, no metabolic drug-drug interactions are expected. Overdose: There is no information on overdose with Tecentriq. Storage: Vials: - Store in a refrigerator at 2°C - 8°C. Keep vial in the outer carton in order to protect from light. DO NOT FREEZE. DO NOT SHAKE. This medicin should not be used after the Expiry Date shown on the pack. The diluted solution for infusion should be used immediately. If the solution is not used immediately, it can be stored for up to 30 days at 2°C-8°C, or 24 hours at ambient temperature (25°C) if prepared under aseptic conditions. This medicinal product must not be mixed with other medicinal products. Shelf-life: 3 Years for Atezolizumab Injection 1200mg/20ml and 2 Years for Atezolizumab Injection 840mg/14ml. Please read full prescribing information before use. Details of Permission or License Number with date: IMP-063/2017 dated 31 March 2017 (1200mg/20ml) and dated 27 Sept 2019 (840mg/14ml) Date of Revision: Current at March 2022, Version 21.0

ABRIDGED PRESCRIBING INFORMATION (Avastin®) SUMMARY OF PRESCRIBING INFORMATION:

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

Generic name: Bevacizumab Injection Brand name: Avastin® Indications: Avastin® is indicated for: (1) For the treatment of Colorectal Cancer (2) Unresectable, advanced, metastatic or recurrent non-squamous non-small cell lung cancer (3) First-line treatment of patients with advanced and/or metastatic Renal Cell Carcinoma (4) For the treatment of Glioblastoma with progressive disease following prior therapy, as a single agent (5) In combination with carboplatin and paclitaxel is indicated for the frontline treatment of advanced (FIGO stages III & IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer (6) In combination with paclitaxel or topotecan or pegylated liposomal doxorubicin in recurrent, platinum-resistant epithelial ovarian cancer (7) In combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent or metastatic carcinoma of the cervix Type of Dosage form: Concentrate for solution for infusion. Avastin is supplied in preservative-free, single-use vials containing Concentrate for solution for infusion, at an active ingredient (Bevacizumab) concentration of 25 mg/mL. Dosage and administration: The recommended dose of Avastin, administered as an intravenous infusion, is as follows: (1) Metastatic Colorectal Cancer: First-line treatment: 5 mg/kg of body weight given once every 2 weeks or 7.5 mg/kg of body weight given once every 3 weeks; Second-line treatment: 5mg/kg or 10 mg/kg of body weight given every 2 weeks or 7.5mg/kg or 15 mg/kg of body weight given once every 3 weeks. Avastin treatment is recommended to be continued until progression of the underlying disease. Patients previously treated with Avastin can continue with Avastin treatment following first progression. (2) Unresectable, advanced or metastatic non-squamous non-small cell lung cancer: 7.5 mg/kg of body weight given once every 3 weeks when used in addition to Cisplatin-based chemotherapy as an intravenous infusion. 15 mg/kg of body weight given once every 3 weeks when used in addition to Carboplatin- based chemotherapy as an intravenous infusion. Avastin is administered in addition to platinum-based chemotherapy for up to 6 cycles of treatment followed by Avastin as a single agent until disease progression. (3) Advanced/metastatic renal cell carcinoma: 10 mg/kg of body weight given once every 2 weeks as an intravenous infusion. Treatment to be continued until progression of the underlying disease. (4) Malignant Glioma (WHO Grade IV) - Glioblastoma: 10 mg/kg of body weight given once every 2 weeks or 15 mg/kg of body weight given once every 3 weeks. Treatment to be continued until progression of the underlying disease. (5) Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer: Front line treatment: 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion when administered in addition to carboplatin and paclitaxel for up to six cycles of treatment followed by continued use of Avastin as single agent for 15 months or until disease progression, whichever occurs earlier; Treatment of recurrent disease: Platinum resistant- 10 mg/kg body weight given once every 2 weeks when administered in combination with one of the following agents - paclitaxel, topotecan given weekly or pegylated liposomal doxorubicin. Alternatively, 15 mg/kg every 3 weeks when administered in combination with topotecan given on days 1-5, every 3 weeks. Treatment to be continued until progression of the underlying disease. (6) Persistent, recurrent or metastatic Cervical Cancer: Avastin is administered in combination with one of the following chemotherapy regimens: paclitaxel and cisplatin or paclitaxel and topotecan. The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion. Treatment to be continued until progression of the underlying disease. Special dosage instructions: Pediatric Use: The safety and efficacy of Avastin in children and adolescents (<18 years) have not been established. Geriatric Use: No dose adjustment is required in patients ≥ 65 years of age. Renal impairment: The safety and efficacy of Avastin have not been studied in patients with renal impairment. Hepatic impairment: The safety and efficacy of Avastin have not been studied in patients with hepatic impairment. Contraindications: Patients with known hypersensitivity to any components of the product, Chinese hamster ovary cell products or other recombinant human or humanised antibodies. Warnings and Precautions: Gastrointestinal Perforations and Fistulae: Patients may be at increased risk for the development of gastrointestinal perforation and gall bladder perforation when treated with Avastin. Avastin should be permanently discontinued in patients who develop gastrointestinal perforation. Patients treated for persistent, recurrent, or metastatic cervical cancer with Avastin may be at increased risk of fistulae between the vagina and any part of the GI tract (Gastrointestinal-vaginal fistulae). Non-GI Fistulae: Patients may be at increased risk for the development of fistulae when treated with Avastin. Permanently discontinue Avastin in patients with TE (tracheoesophageal) fistula or any Grade 4 fistula. Hemorrhage: Patients treated with Avastin have an increased risk of hemorrhage, especially tumor-associated hemorrhage. Avastin should be permanently discontinued in patients who experience Grade 3 or 4 bleeding during Avastin therapy. Patients with untreated CNS metastases should be monitored for signs and symptoms of CNS bleeding, and Avastin treatment should be discontinued in case of intracranial bleeding. There is no information on the safety profile of Avastin in patients with congenital bleeding diathesis, acquired coagulopathy or in patients receiving full dose of anticoagulants for the treatment of thromboembolism prior to starting Avastin treatment, as such patients were excluded from clinical trials. Therefore, caution should be exercised before initiating Avastin therapy in these patients. Pulmonary Hemorrhage/ Hemoptysis: Patients with non-small cell lung cancer treated with Avastin may be at risk for serious, and in some cases fatal, pulmonary hemorrhage/hemoptysis. Patients with recent pulmonary hemorrhage/hemoptysis (≥ 1/2 teaspoon red blood) should not be treated with Avastin. Hypertension: An increased incidence of hypertension was observed in patients treated with Avastin. Clinical safety data suggest that the incidence of hypertension is likely to be dose- dependent. Pre-existing hypertension should be adequately controlled before starting Avastin treatment. Monitoring of blood pressure is recommended during Avastin therapy. Avastin should be permanently discontinued if hypertension cannot be adequately controlled with antihypertensive therapy or if the patient develops hypertensive crisis or hypertensive encephalopathy. Posterior Reversible Encephalopathy Syndrome (PRES): There have been rare reports of Avastin-treated patients developing signs and symptoms that are consistent with Posterior Reversible Encephalopathy Syndrome (PRES), a rare neurological disorder. In patients developing PRES, treatment of specific symptoms including control of hypertension is recommended along with discontinuation of Avastin. The safety of reinitiating Avastin therapy in patients previously experiencing PRES is not known. Arterial thromboembolism: In clinical trials, the incidence of arterial thromboembolism events including cerebrovascular accidents, transient ischemic attack (TIA) and myocardial infarction (MI) was higher in patients receiving Avastin in combination with chemotherapy compared to those who received chemotherapy alone. Avastin should be permanently discontinued in patients who develop arterial thromboembolic events. Patients receiving Avastin plus chemotherapy with a history of arterial thromboembolism, diabetes or age greater than 65, was associated with an increased risk of arterial thromboembolic events during Avastin therapy. Caution should be taken when treating such patients with Avastin. Venous thromboembolism: Patients may be at risk of developing venous thromboembolic events, including pulmonary embolism under Avastin treatment. Avastin should be discontinued in patients with life-threatening (Grade 4) venous thromboembolic events, including pulmonary embolism; patients with thromboembolic events 4-Grade 3 need to be closely monitored. Congestive Heart Failure: Events consistent with congestive heart failure (CHF) were reported in clinical trials. Caution should be exercised when treating patients with clinically significant cardiovascular disease such as pre-existing coronary artery disease or congestive heart failure with Avastin. Neutropenia: Increased rates of Severe neutropenia, febrile neutropenia, or infection with severe neutropenia (including some fatalities) have been observed in patients treated with some myelotoxic chemotherapy regimens plus Avastin in comparison to chemotherapy alone. Proteinuria: In clinical trials, the incidence of proteinuria was higher in patients receiving Avastin in combination with chemotherapy compared to those who received chemotherapy alone. Grade 4 proteinuria (nephrotic syndrome) was seen in up to 1.4% of patients treated with Avastin. In the event of nephrotic syndrome Avastin treatment should be permanently discontinued. Wound healing: Avastin may adversely affect the wound healing process. Serious wound healing complications with a fatal outcome have been reported. Avastin therapy should not be initiated for at least 28 days following major surgery or until the surgical wound is fully healed. In patients who experience wound healing complications during Avastin treatment, Avastin should be withheld until the wound is fully healed. Avastin therapy should be withheld for elective surgery. Necrotising fasciitis including fatal cases, has rarely been reported in patients treated with Avastin; usually secondary to wound healing complications, gastrointestinal perforation or fistula formation. Avastin therapy should be discontinued in patients who develop necrotizing fasciitis, and appropriate treatment should be promptly initiated. Hypersensitivity reactions, infusion reactions: Patients may be at risk of developing infusion / hypersensitivity reactions. If a reaction occurs, the infusion should be discontinued and appropriate medical therapies should be administered. A systematic premedication is not warranted. Severe eye infections following compounding for unapproved intravitreal use: Individual cases and clusters of serious ocular adverse events have been reported (including infectious endophthalmitis and other ocular inflammatory conditions) following unapproved intravitreal use of Avastin compounded from vials approved for intravenous administration in cancer patients. Some of these events have resulted in various degrees of visual loss, including permanent blindness. Ovarian failure/fertility: Avastin may impair female fertility. Therefore, fertility preservation strategies should be discussed with women of child-bearing potential prior to starting treatment with Avastin. Use in Special Populations: Females and Males of Reproductive Potential: Fertility: Avastin may impair female fertility. Women of child-bearing potential should be advised of fertility preservation strategies prior to starting treatment with Avastin,. After discontinuation of bevacizumab treatment, ovarian function recovered in the majority of patients. Long term effects of the treatment with bevacizumab on fertility are unknown. Contraception: In women with childbearing potential, appropriate contraceptive measures should be used during Avastin therapy and for at least 6 months following the last dose of Avastin. Pregnancy: Avastin should not be used during pregnancy. Lactation: Women should be advised to discontinue nursing during Avastin therapy and not to breast feed for at least 6 months following the last dose of Avastin. Pediatric Use: Avastin is not approved for use in patients under the age of 18 years. Undesirable effects: From Clinical Trials, the very commonly reported adverse drug reactions include febrile neutropenia, leucopenia, neutropenia, thrombocytopenia, peripheral sensory neuropathy, hypertension, diarrhoea, nausea, vomiting, abdominal pain, asthenia, fatigue, anorexia , hypomagnesaemia, hyponatraemia, dysgeusia, headache, dysarthria, eye disorder, lacrimation increased, epistaxis, rhinitis, cough, dyspnoea, constipation, stomatitis, rectal haemorrhage, ovarian failure, exfoliative dermatitis, dry skin, skin discolouration, arthralgia, proteinuria, pyrexia, pain, mucosal inflammation, weight decreased. Post Marketing Experience : Adverse drug reactions identified from post marketing experience include hypertensive encephalopathy (very rare), Necrotising fasciitis (rare), PRES (rare), Renal Thrombotic Microangiopathy, Nasal septum perforation, Pulmonary hypertension, dysphonia, Gastrointestinal ulcer, Gallbladder perforation, Hypersensitivity, Infusion reactions, Osteonecrosis of the Jaw (ONJ) and Osteonecrosis at other sites, Foetal abnormalities. Interactions with other medicinal products and other forms of interaction: Effect of antineoplastic agents on bevacizumab pharmacokinetics: No clinically relevant interaction of co-administered chemotherapy on bevacizumab pharmacokinetics was observed based on the results of population pharmacokinetic analyses. Effect of bevacizumab on the pharmacokinetics of other antineoplastic agents: No clinically relevant interaction of bevacizumab was observed on the pharmacokinetics of co-administered interferon-alfa 2a, erlotinib (and its active metabolite OSI-420), or the chemotherapies irinotecan (and its active metabolite SN38), capecitabine, oxaliplatin (as determined by measurement of free and total platinum), and cisplatin. In two clinical studies of metastatic renal cell carcinoma, microangiopathic haemolytic anaemia (MAHA) was reported in 7 of 19 patients treated with bevacizumab (10 mg/kg every two weeks) and sunitinib malate (50 mg daily) combination. Overdose: The highest dose tested in humans (20 mg/kg of body weight every 2 weeks, intravenous) was associated with severe migraine in several patients. Storage condition: Store vials in a refrigerator at 2°C-8°C. Keep vial in the outer carton in order to protect from light. DO NOT FREEZE. DO NOT SHAKE. Special Instructions for Use: Avastin infusions should not be administered or mixed with dextrose or glucose solutions. Do not administer as an intravenous push or bolus. Use sterile needle and syringe to prepare Avastin. Shelf-life of the solution for infusion containing the reconstituted product: Avastin does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution. Chemical and physical in-use stability has been demonstrated for 30 days at 2°C-8°C plus an additional 48 hours at 2°C-30°C in 0.9% sodium chloride solution. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions. Shelf life: 24 months Packs: Each pack contains a single-use vial of 100mg/4ml or 400mg/16ml. Vials 100 mg/4ml; Pack of 1 Vial (4 mL) containing Bevacizumab concentrate for solution for infusion 100mg (25mg/ml). Vials 400 mg/16ml: Pack of 1 Vial (16 mL) containing Bevacizumab concentrate for solution for infusion 400mg (25mg/ml). Please read full prescribing information before usage. Details of Permission or License Number with date: Import-1992/04 dated 17 January 2005 Date of Revision: Current at October 2021, version 19.0

Roche

Marketed in India by :
Roche Products (India) Pvt. Ltd.
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5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

22nd - 24th JULY 2022

One dose
Dual action
5-day prevention[1-5]

Akynzeo®

netupitant/palonosetron

PREVENTION MADE SIMPLE

Ref: 1. Aapro M et al. Ann Oncol. 2014; 25(7):1328–33. 2. Hesketh PJ et al. Ann Oncol. 2014; 25(7):1340–6. 3. Gralla RJ et al. Ann Oncol. 2014; 25(7):1333–9. 4. Rojas C et al. Eur J Pharmacol. 2014; 722:26–37. 5. AKYNZEO® (netupitant/palonosetron HCl) capsules. Summary of Product Characteristics.

AKYNZEO® 300 mg/0.5 mg hard capsules
ACTIVE INGREDIENTS: 300 mg of netupitant, and 0.26 mg of palonosetron hydrochloride equivalent to 0.5 mg of palonosetron. **INDICATIONS:** Akynzeo® is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.**POSOLOGY AND METHOD OF ADMINISTRATION:** One hard capsule should be administered approximately one hour prior to the start of each chemotherapy cycle. The hard capsule should be swallowed whole and can be taken with or without food. The recommended oral dexamethasone dose should be reduced by approximately 50%. No dosage adjustment is necessary for elderly patients. Caution should be exercised when using in patients over 75 years. The safety and efficacy in the paediatric population have not been established. Dosage adjustment is not considered necessary in patients with mild to severe renal impairment. Use in end-stage renal patients requiring hemodialysis should be avoided. No dosage adjustment is necessary for patients with mild or moderate hepatic impairment (Child-Pugh score 5–6). Caution should be used with patients with severe hepatic impairment (Child Pugh score ≥ 9). **CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients. Pregnancy. **WARNING AND PRECAUTIONS:** History of constipation or signs of subacute intestinal obstruction. Serotonin syndrome either alone or in combination with selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs).The use of medicinal products that increase the QT interval or the use in patients who have or are likely to develop prolongation of the QT interval. Systemic exposure to other medicines metabolised by CYP3A4. Breastfeeding should be discontinued during treatment with Akynzeo®. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Akynzeo®. Patients with known hypersensitivity to peanut or soya should be monitored closely for signs of an allergic reaction. **INTERACTIONS:** concomitant use of drugs that induce CYP3A4 activity can decrease efficacy of Akynzeo®. Akynzeo® can increase plasma concentrations of drugs that are metabolised via CYP3A4. The inhibitory effect on CYP3A4 can last for multiple days. Dexamethasone doses should be reduced when given with Akynzeo®. Exposure to docetaxel and etoposide was increased when co-administered with Akynzeo®.No consistent effect was seen with cyclophosphamide after netupitant co-administration. The potential effects of increased plasma concentrations of erythromycin, midazolam or other benzodiazepines metabolised via CYP3A4 (alprazolam, triazolam) when administering with Akynzeo® should be considered. Concomitant use of Akynzeo® in patients on chronic use of a strong CYP3A4 inducer such as rifampicin should be avoided as this may decrease the efficacy of Akynzeo®. Concomitant administration with strong CYP3A4 inhibitors such as ketoconazole should be approached with caution. Caution is recommended when netupitant is combined with an oral substrate of UGT2B7 (e.g.zidovudine, valproic acid, morphine) as in vitro data shows that netupitant inhibits this enzyme.**FERTILITY, PREGNANCY AND LACTATION:** Women of childbearing potential should not be pregnant or become pregnant while on treatment with Akynzeo® and a pregnancy test should be performed on all premenopausal women prior to treatment. Women of childbearing potential must use effective contraception during therapy and up to one month after treatment with Akynzeo®. Akynzeo® should not be used during breastfeeding; it should be discontinued during treatment and for 1 month after the last dose with AKYNZEO®. **ADVERSE REACTIONS:** Common: Headache, Constipation, Fatigue, Uncommon: Neutropenia, Leucocytosis, Decreased appetite, Insomnia, Dizziness, Vertigo, Atrioventricular block first degree, Cardiomyopathy, Conduction disorder, Hypertension, Hiccups, Abdominal pain, Diarrhoea, Dyspepsia, Flatulence, Nausea, Alopecia, Urticaria, Asthenia, Liver transaminases increased, Blood alkaline phosphatase increased, Blood creatinine increased, Electrocardiogram QT prolonged, Rare: Cystitis, Leukopenia, Lymphocytosis, Hypokalaemia, Acute psychosis, Mood altered, Sleep disorder, Hypoaesthesia, Conjunctivitis, Vision blurred, Arrhythmia, Atrioventricular block second degree, Bundle branch block, Mitral valve incompetence, Myocardial ischaemia, Ventricular extrasystoles, Hypotension, Dysphagia, Tongue coated, Back pain, Feeling hot, Non-cardiac chest pain, Product taste abnormal, Blood bilirubin increased, Blood creatine phosphokinase MB increased, Electrocardiogram ST segment depression, Electrocardiogram ST-T segment abnormal, Troponin increased, Very rare: anaphylaxis, anaphylactic/ anaphylactoid reactions and shock have been reported from the post-marketing use of intravenous palonosetron. Overdose: No specific information is available on the treatment of overdose with Akynzeo®. In case of overdose Akynzeo® should be discontinued and general supportive treatment and monitoring should be provided.

Legal category Medical Prescription Product. Marketing authorisation number
EU/1/15/1001001, Marketing authorisation holder Helsinn Birex Pharmaceuticals Ltd, Damastown, Mulhuddart, Dublin 15, Ireland.
Reporting suspected adverse reactions after authorisation of Akynzeo® is important, it allows continued monitoring of the benefit/risk balance of Akynzeo®. Healthcare professionals are asked to report any suspected adverse reactions according to their national provisions. Adverse reactions should also be reported to Helsinn Birex Pharmaceuticals Ltd., (address as above) Tel: +353 86 8365321
Akynzeo® is a registered trademark of Helsinn Healthcare SA, Switzerland.
Akynzeo® is marketed in India exclusively by Glenmark Pharmaceuticals

ABPI Ref.: Akynzeo/26th June 2020
For further product related query contact: Glenmark Pharmaceuticals Limited (GPL), Corporate Enclave, B, D, Sawant Marg, Chakala, Andheri (E), Mumbai – 99, Email id: global.customerservice@glenmarkpharma.com
For any adverse event related to Glenmark marketed product contact on global.customerservice@glenmarkpharma.com

AKY/0622/04

5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

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For the management of advanced HCC

Lenvenib®
Lenvatinib 4mg/10mg Capsules
a NEW standard

Cabozat™
Cabozantinib 20/40 mg Tablets
Improve Survival with a Masterstroke

- Developed **in house** right from basic API to finished product*
- **Bioequivalent** to the innovator
- Manufactured in **USFDA** approved plant for benchmark quality*

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* Data on file.

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