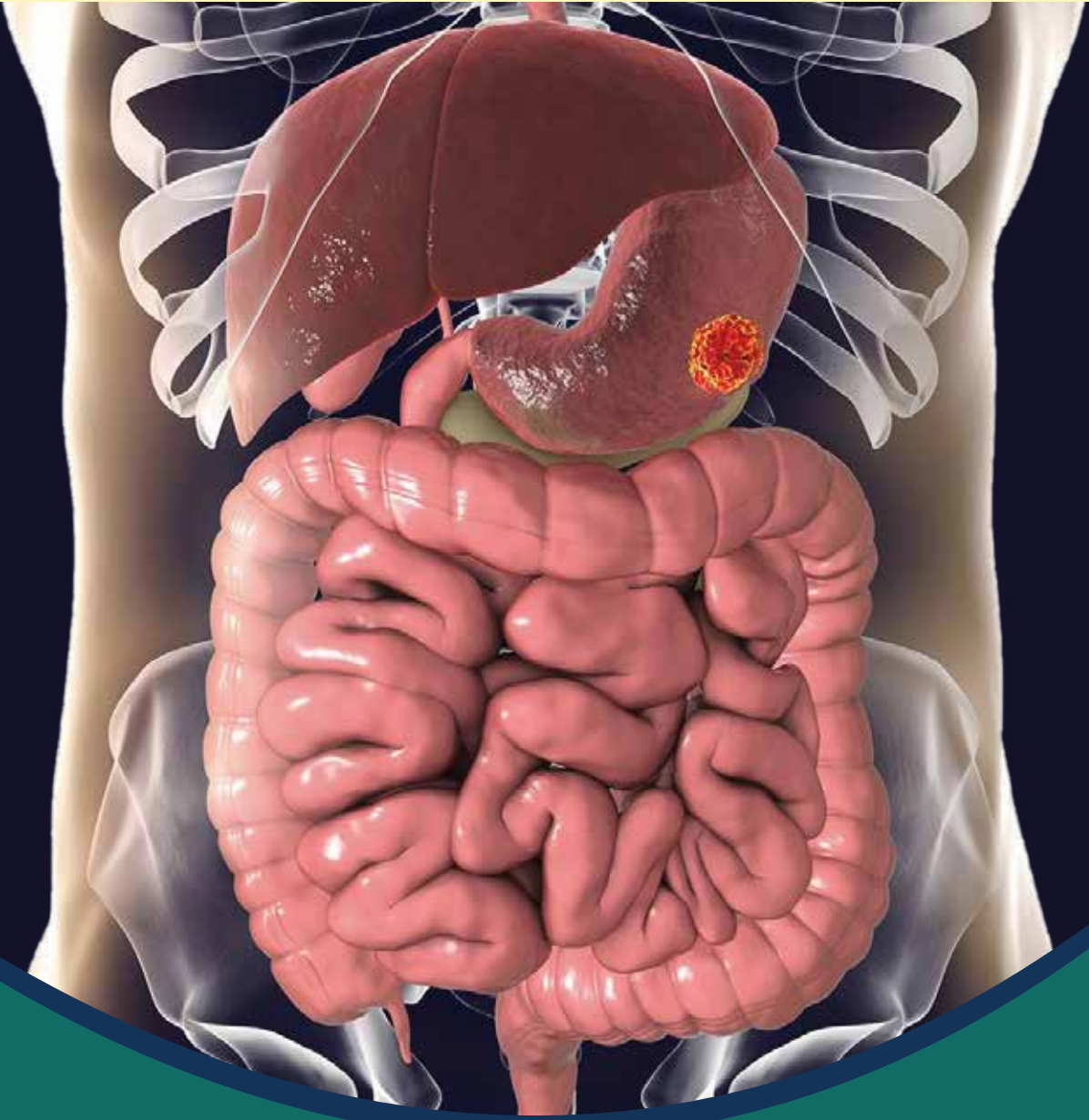




5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS



Virtual Meet

22nd - 24th
JULY 2022

ORGANISING
TEAM



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



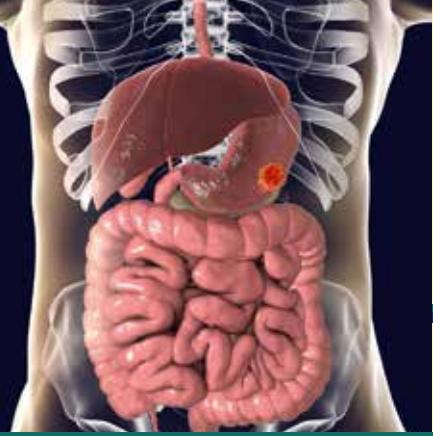
Dr. Tejinder Singh
Sr. Consultant Medical Oncologist
Apollo Cancer Center,
Apollo Hospital, Mumbai



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

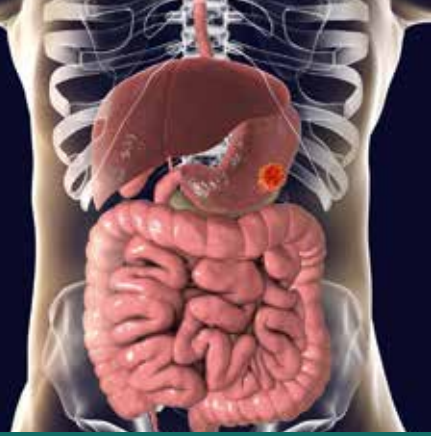
Sr. Consultant Medical Oncologist
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Apollo Hospital, Mumbai

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5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

22nd - 24th JULY 2022

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

22nd - 24th JULY 2022

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
Recent 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



5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

22nd - 24th JULY 2022

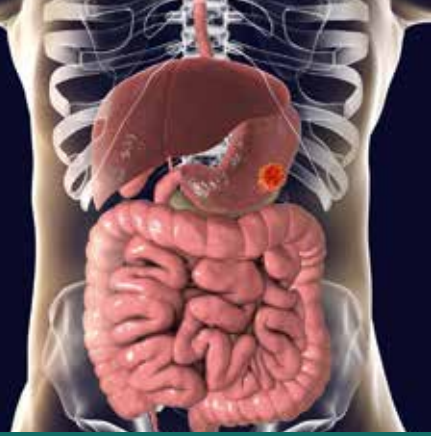
Day 2 | 23rd July 2022 Scientific Program

Session 1 : Esophagus/Stomach Cancers

6:00pm – 6:10pm	<p>Chairpersons - Dr. Shirish Alurkar Dr. Girish Phadke</p> <p>Updates in Surgical Management of Localized EG Cancers Speaker: Dr. M. Satish Kumar</p>
6:10pm – 6:20pm	<p>Management of Metastatic EG Cancer Speaker: Dr. Pritam Kalaskar</p>
6:20pm – 6:40pm	<p>Should all Patients with EG Cancer Receive Immunotherapy? Yes – Dr. M. Vamshi Krishna No – Dr. Peush Bajpai Debate Moderator : Dr. Bharat Bhosale</p>
6:40pm – 7:10pm	<p>Chairpersons - Dr. Satish Midha Dr. Atul Sharma</p> <p>Panel Discussion: Practice Changing Papers in Esophageal / Gastric Cancers Moderator: Dr. Vedant Kabra</p> <p>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</p>

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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



5TH ANNUAL INTERNATIONAL REVIEW ON GI CANCERS

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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 Bhoirwal
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

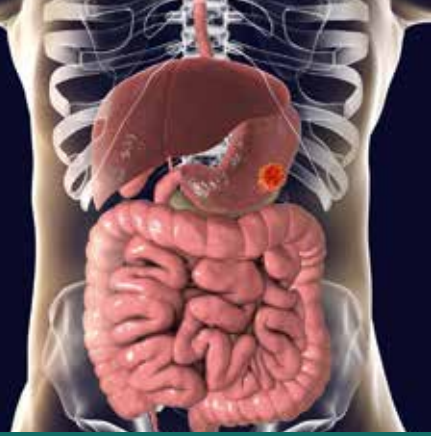
6:55pm – 7:20pm

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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Amey Kadam

Conference Secretariat

rrcg.amey@gmail.com | Mobile +91 98212 41572

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20 mg

Tegafur + Gimeracil + Oteracil Potassium



for

Advanced Gastric Cancer together with Cisplatin



Tegafur

Prodrug of
5-fluorouracil (5-FU)
Replacement for infusional 5-
FU therapy

**Increased
Convenience**

Oteracil

Modulator to reduce
unwanted
5-FU-induced
gastrointestinal toxicity,
as it is related to
phosphorylation of 5-FU

**Reduced
Toxicity**

Gimeracil

Modulator to enhance the
efficacy of tegafur by
inhibiting catabolism and
subsequent inactivation of 5-
FU by inhibiting the enzyme
DPD, so that concentrations
of 5-FU are maintained for a
longer period of time

**Enhanced
Efficacy**



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22nd - 24th JULY 2022

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)



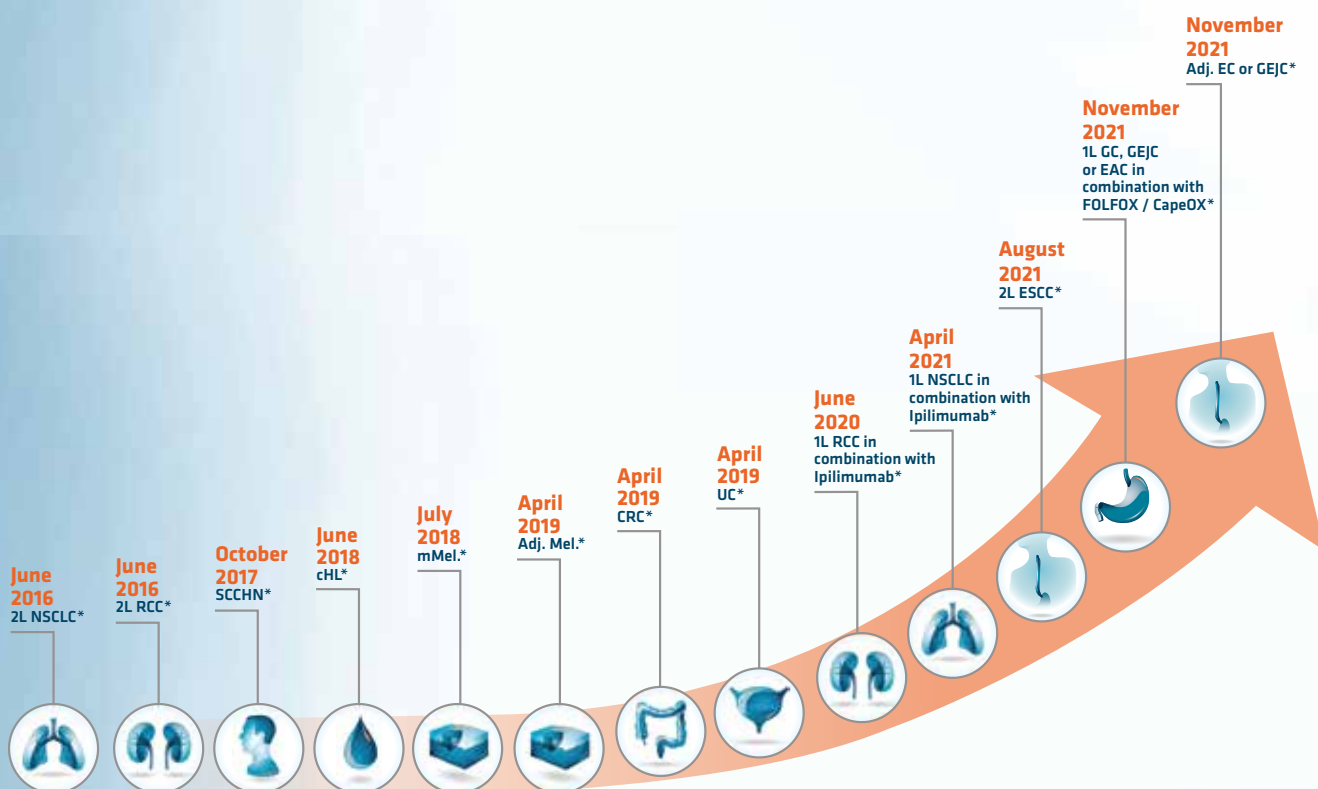
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NOW
APPROVED IN
13
INDICATIONS

OPDYTA®
(nivolumab)
EXPECT MORE.DO MORE.

OPDYTA® is the only IO approved in 13 indications in India



NSCLC: Non-small Cell Lung Cancer; RCC: Renal Cell Carcinoma; SCCN: Squamous Cell Carcinoma of the Head and Neck; mMel.: metastatic Melanoma; Adj. Mel.: Adjuvant Melanoma; CRC: Colorectal Cancer; UC: Urothelial Carcinoma; cHL: Classical Hodgkin Lymphoma; ESCC: Esophageal Squamous Cell Carcinoma; Adj. EC/GEJC: Adjuvant treatment of resected Esophageal Cancer or Gastroesophageal Junction Cancer; GC: Gastric Cancer; GEJC: Gastroesophageal Junction Cancer; EAC: Esophageal Adenocarcinoma; FOLFOX: Folinic acid, fluorouracil, and oxaliplatin; CapeOX: Capecitabine plus oxaliplatin

IO: Immuno-Oncology
*Please refer to complete indication wording mentioned below in API.
OPDYTA® (Nivolumab) India Prescribing Information version 11 dated 11 Aug 2021.
Kindly refer to the full prescribing information before.

Abridged Prescribing Information

To be sold by retail on the prescription of a Registered Oncologist only.

OPDYTA® 10 mg/mL concentrate for solution for infusion. Composition: One vial of 4 mL contains 40 mg of nivolumab; One vial of 10 mL contains 100 mg of nivolumab. **Therapeutic Indications:** Non-Small Cell Lung Cancer (NSCLC): As a single agent for the treatment of locally advanced or metastatic NSCLC after prior chemotherapy; Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. Nivolumab, in combination with ipilimumab 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; Renal Cell Carcinoma (RCC): As a single agent for the treatment of patients with advanced RCC after prior therapy in adults and for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab; Squamous Cell Carcinoma of the Head and Neck (SCCHN): As monotherapy for the treatment of recurrent or metastatic SCCHN after platinum-based therapy; Melanoma: As a single agent for the treatment of patients with BRAF V600 wildtype unresectable or metastatic melanoma, as a single agent for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma. For the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting; Classical Hodgkin Lymphoma (cHL): For the treatment of adult patients with cHL that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin / 3 or more lines of systemic therapy that includes autologous HSCT; Hepatocellular Carcinoma (HCC): For the treatment of patients with HCC who have been previously treated with sorafenib; Urothelial Carcinoma (UC): For the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy OR have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; Colorectal Cancer (CRC): As monotherapy for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Esophageal Squamous Cell Carcinoma (ESCC): For the treatment of patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy; Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (GC, GEJC or EAC): Nivolumab, in combination with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma; Adjuvant treatment of Resected Esophageal or Gastroesophageal Junction Cancer (EC or GEJC): As monotherapy for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT). **Dosage and administration: Nivolumab as monotherapy (NSCLC, RCC, SCCHN, melanoma, cHL, HCC, UC, CRC) - 3 mg/kg administered intravenously every 2 weeks over 30 minutes. Nivolumab as monotherapy for ESCC, EC and GEJC: Weight-based dosing - 3 mg/kg every 2 weeks over a period of 30 minutes Or Flat dosing - 240 mg every 2 weeks or 480 mg every 4 weeks. For adjuvant treatment, the maximum duration of nivolumab is 12 months. Nivolumab in combination with fluoropyrimidine- and platinum-containing chemotherapy GC, GEJC and EAC: 360 mg Nivolumab intravenously over 30 minutes in combination fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks or 240 mg nivolumab intravenously over 30 minutes in combination with fluoropyrimidine and platinum-based chemotherapy every 2 weeks until disease progression or unacceptable toxicity. The maximum treatment duration for nivolumab is 24 months. Nivolumab in combination with ipilimumab and platinum-based chemotherapy (NSCLC): The recommended dose is 360 mg nivolumab administered as an intravenous infusion over 30 minutes every 3 weeks in combination with 1 mg/kg ipilimumab administered as an intravenous infusion over 30 minutes every 6 weeks, and platinum chemotherapy administered every 3 weeks. After completion of 2 cycles of chemotherapy, treatment is continued with 360 mg nivolumab administered as an intravenous infusion every 3 weeks in combination with 1 mg/kg ipilimumab every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. Nivolumab in combination with ipilimumab (RCC): Combination phase: nivolumab 3 mg/kg over 30 minutes every 3 weeks for the first 4 doses in combination with ipilimumab 1 mg/kg over 30 minutes, followed by the single-agent phase. Single-agent phase: 3 mg/kg every 2 weeks over 30 minutes. The first dose of nivolumab monotherapy should be administered 3 weeks following the last dose of the combination of nivolumab and ipilimumab. When administered in combination with ipilimumab, nivolumab should be given first followed by ipilimumab on the same day. Safety related information. Contraindications: None. Warnings and Precautions: Recommended treatment modifications for nivolumab or nivolumab in combination with ipilimumab. Immune-related pneumonitis: Withhold for grade 2 and permanently discontinue for grade 3 or 4 pneumonitis. Immune-related colitis: Withhold for Grade 2 diarrhea or colitis. Withhold Nivolumab monotherapy for Grade 3 diarrhea or colitis. Permanently discontinue nivolumab + ipilimumab for Grade 3 or 4 diarrhea or colitis. Permanently discontinue nivolumab monotherapy for Grade 4 diarrhea or colitis. Immune-related hepatitis: Monitor for change in liver function. Withhold for grade 2 and permanently discontinue for grade 3 or 4 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin. Immune-related nephritis and renal dysfunction: Monitor for changes in renal function. Withhold for grade 2 and permanently discontinue for grade 4 serum creatinine elevation. Immune-related endocrinopathies: Monitor for changes in thyroid function. Initiate thyroid hormone replacement as needed. Monitor for hyperglycemia. Withhold for symptomatic grade 2 or 3 and permanently discontinue for grade 4 hypophosphatemia. Withhold for grade 2 and permanently discontinue for grade 3 or 4 adrenal insufficiency. Withhold for symptomatic grade 2 or 3 and permanently discontinue for grade 4 hypothyroidism or hyperthyroidism. Withhold for grade 3 and permanently discontinue for grade 4 diabetes. Immune-related skin adverse reactions: Withhold for grade 3 rash or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) and permanently discontinue for grade 4 rash or confirmed SJS/TEN. Other immune-related adverse reactions: Withhold for grade 3 (first occurrence) and permanently discontinue for grade 3 myocarditis, grade 4 or recurrent grade 3, persistent grade 2 or 3 despite treatment modification, inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day. When nivolumab is administered in combination with ipilimumab, if either agent is withheld, the other agent should also be withheld. If dosing is resumed after a delay, either the combination treatment or nivolumab monotherapy could be resumed based on the evaluation of the individual patient. Complications of allogeneic hematopoietic stem cell transplant (HSCT) after Nivolumab: Monitor for transplant-related complications, including GVHD. Fatal cases have been reported in clinical studies. Infusion reaction: Discontinue for severe and life-threatening infusion reactions. Patients with mild or moderate infusion reaction may receive nivolumab or nivolumab in combination with ipilimumab with close monitoring and use of premedication according to local treatment guidelines. Increased mortality in patients with multiple myeloma [not an approved indication] when a PD-1 blocking antibody is added to a thalidomide analogue and dexamethasone: Treatment of patients with multiple myeloma with a PD-1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials. Drug Interactions: Inhibition or induction of cytochrome P450 (CYP) enzymes or other drug metabolizing enzymes by coadministered medicinal products is not anticipated to affect the pharmacokinetics of nivolumab. The use of systemic corticosteroids and other immunosuppressants at baseline, before starting nivolumab, should be avoided. However, these can be used after starting nivolumab to treat immune-related adverse reactions. Pregnancy: Not recommended during pregnancy and in women of childbearing potential not using effective contraception unless the clinical benefit outweighs the potential risk. Women should be advised to use effective contraception for at least 5 months following the last dose of nivolumab. Nursing Mothers: Discontinue breastfeeding. Pediatric Use: The safety and efficacy have not been established. Geriatric Use: No dose adjustment is required for elderly patients (≥65 years). Hepatic Impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Renal Impairment: No specific dose adjustment is necessary in patients with mild to moderate renal impairment. Adverse Reactions: Fatigue, rash, musculoskeletal pain, pruritus, diarrhea, nausea, cough, dyspnea, constipation, decreased appetite, back pain, arthralgia, upper respiratory tract infection, pyrexia, headache, abdominal pain, vomiting, neutropenia, hypothyroidism. Nivolumab is associated with immune-related adverse reactions. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of Nivolumab. Overdose: Closely monitor for signs and symptoms of adverse reactions and institute appropriate symptomatic treatment. Storage: Store in a refrigerator (2°C - 8°C). Do not freeze. API based on prescribing information version 11 dated 11 Aug 2021. Issued - 11 Jan 2022.**

Bristol Myers Squibb™

For further information, please contact-
Bristol-Myers Squibb India Private Limited, 6th floor, Tower 1, One International Center, S.B. Marg, Elphinstone (W), Mumbai - 400013. Tel: + 91 22 6628 8600

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7356-IN-2200012

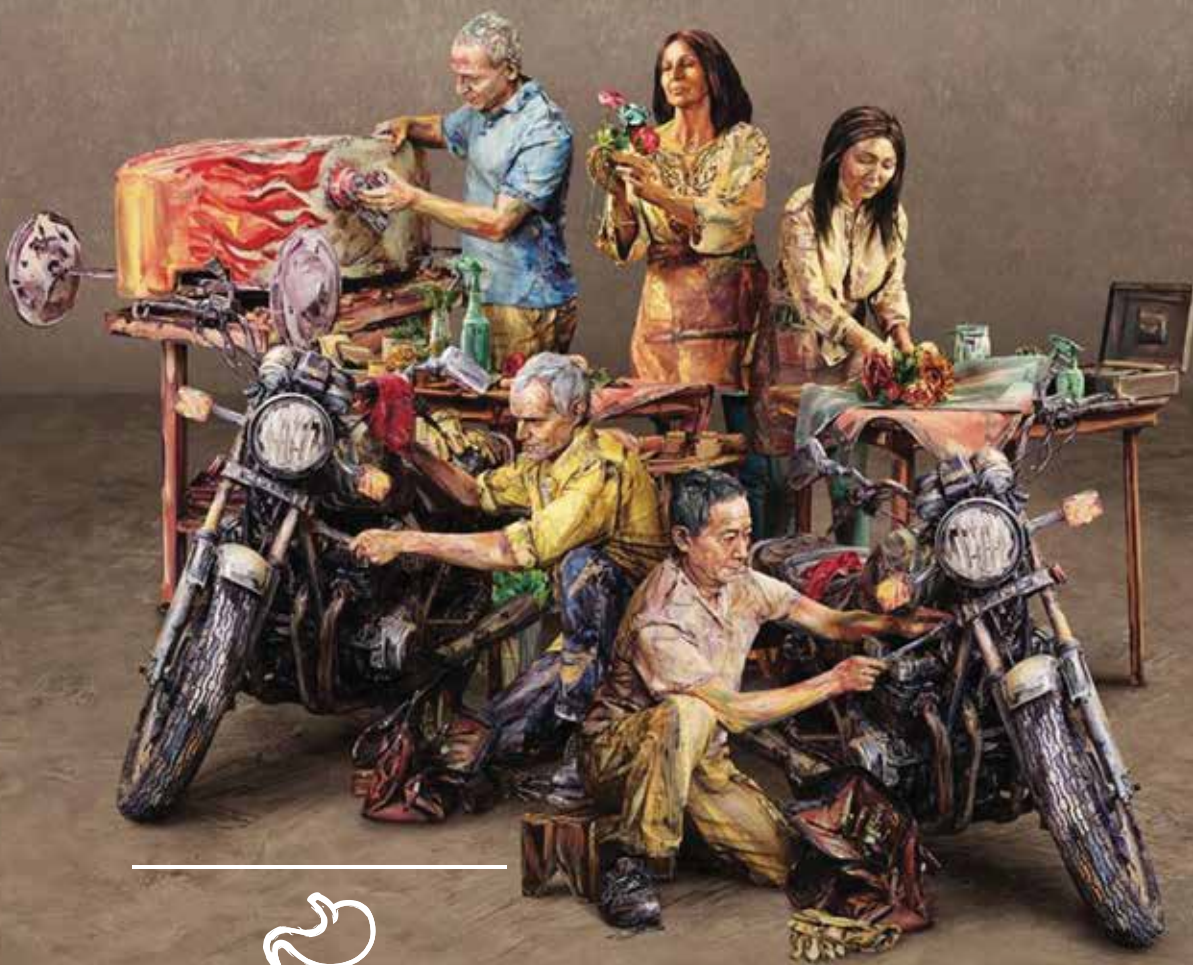


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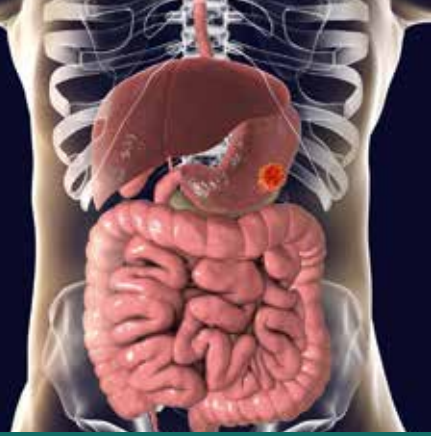
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A novel powered circular stapler designed for creating secure anastomoses.
Med Devices Diagn Eng. 2. DOI: 10.15761/MDDC1000123



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