IMMUNO-ONCOLOGY SOCIETY OF INDIA

2nd I-OSI Annual Congress 2020

30TH-31ST OCTOBER,
1ST NOVEMBER 2020

"Immuno-Oncology towards 2021:
Reboot, Resolve and Evolve"

LIVE **I-OSI Virtual Congress**

Organizing Secretary

Dr. Jyoti Bajpai, MD, DM
Founder General Secretary, I-OSI
Professor, Medical Oncology,
Tata Memorial Centre, Mumbai

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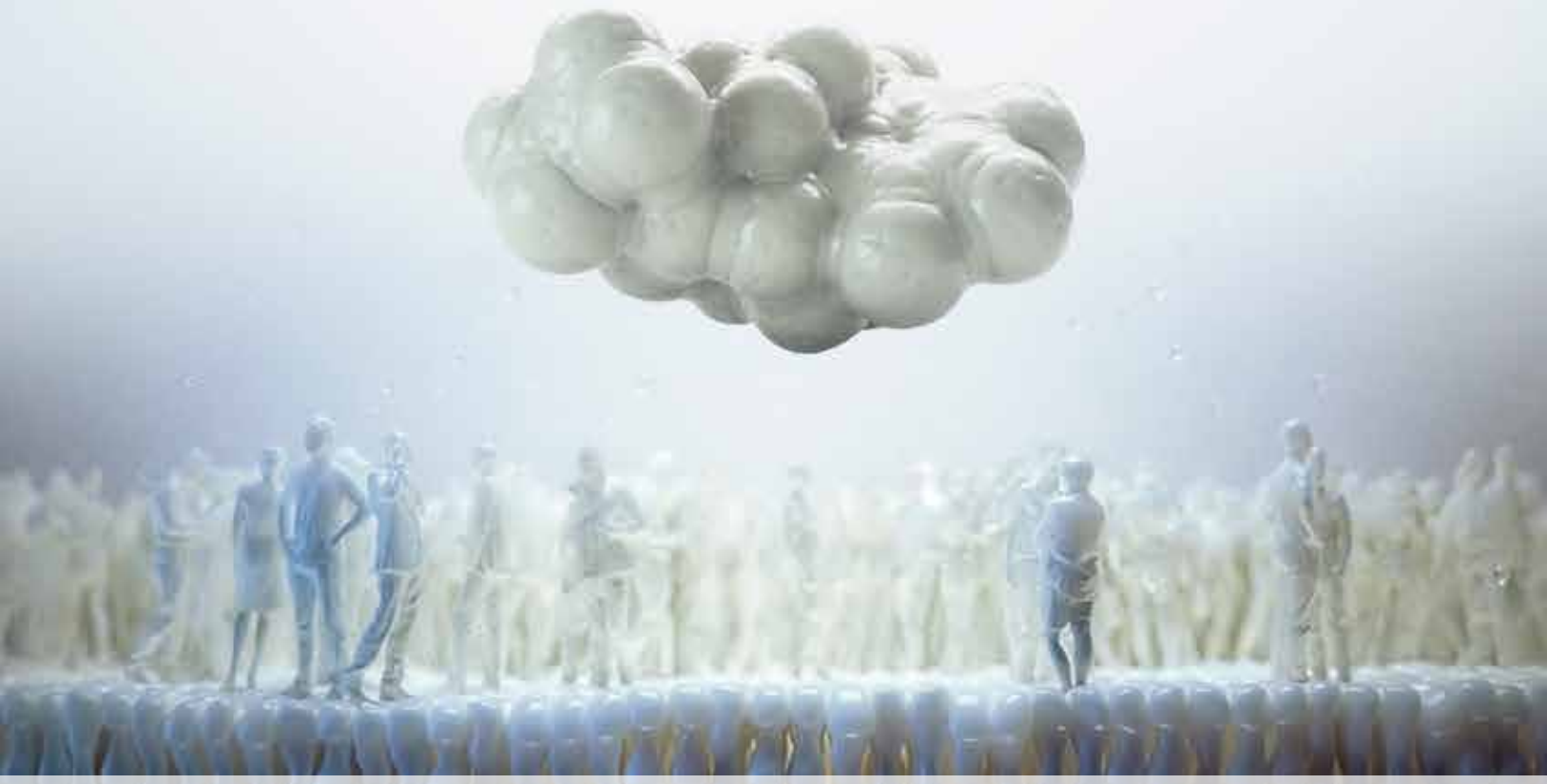

Participants will get 4 CME credit points

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Dear Friends,

My greetings and well wishes to all of you for your good health and inspiring work in cancer and community care.

On behalf of the Immuno-oncology Society of India(I-OSI), I am pleased to welcome you for the 2nd Annual National Congress to be held as a three days virtual programme on October 30th to 31st (4 PM - 9 PM India Standard Time) and Nov 1st, 2020 (9 AM - 1.30 PM IST).

This conference will assess the current state of immuno-oncology that highlights for cancer care professionals the current research, utilization trends, and coming advances for immunotherapies. Hence, the theme of this year's conference is **"Immuno-Oncology towards 2021: Reboot, Resolve and Evolve"**.

The huge learning curve that immuno-oncology presented has significantly flattened out just by virtue of the explosive availability of immuno-oncology therapies in cancer care. In many cases, it has become the standard of care, and if you want to practice oncology today, you have to keep yourself abreast with the new tricks. The IOSICON 2020 therefore aims to meet these needs of multidisciplinary care teams and describes next steps for supporting optimal delivery of immunotherapies.

With 3876 agents and 469 targets in 2019 the recent white paper points to the likelihood of further expansion of immunotherapy to treat more patients in the future. Factors that support this belief include the emergence of checkpoint inhibitors as feasible therapies in a variety of adjuvant and neoadjuvant settings, an increase in utilization of immuno-oncology therapies as part of combination regimens or in sequence with chemotherapy or targeted agents, and the increase of immuno-oncology delivery in the community setting.

Additionally, I-OSICON will also try to address survivorship needs, which includes unpredictable and delayed immune-related adverse events, follow-up, and psychosocial support.

For over 2 years, I-OSI has been the leader in promoting tumor immunology and advancing cancer immunotherapy education, information and research in India. As the paradigm in cancer treatment changes, I-OSI Annual Meeting continues to lead and drive the numerous advances our field is making.

We have various sponsorship opportunities for pharma partners and we request you to get in touch with our event manager and discuss the same.

Looking forward to your whole hearted support.

Regards,

Dr. Jyoti Bajpai,
Organizing Secretary, I-OSI 2020
Founder General Secretary: Immuno-Oncology Society of India (I-OSI)
Professor, Medical Oncology, Tata Memorial Centre, Mumbai, India

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CONFERENCE COMMITTEE	
Patrons	Dr. R. A. Badwe Dr. S. H. Advani Dr. Asha Kapadia
Organising Chairpersons	Dr. Shubhada Chiplunkar Dr. S. D. Banavali Dr. Hemant Malhotra
Organising Secretary	Dr. Jyoti Bajpai
Joint Organising Secretaries	Dr. Vivek Radhakrishnan Dr. Rahul Purwar
Scientific Committee Chair	Dr. Atul Sharma Dr. Kumar Prabhash Dr. (Surg Cdr) Gaurav Narula
Advisory Committee	Dr. B. K.Smruti Dr. Vikram Mathews Dr. Reena Nair Dr. Moni Abraham Kuriakose Dr. Rakesh Jalali Dr. Senthil Rajappa Dr. Girdhari Lal Dr. Amit Awasthi

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INVITED INTERNATIONAL FACULTY

Dr. James P. Allison
Nobel Laureate for Physiology and Medicine
Regental Professor & Chair, Department of Immunology,
Olga Keith Wiess Distinguished University
Chair for Cancer Research,
Director, Parker Institute for Cancer Research,
Executive Director, Immunotherapy Platform,
MD Anderson Cancer Center, USA

Dr. Jedd D. Wolchok
Chief, Immuno-Oncology Service, Human Oncology and Pathogenesis Program
Lloyd J. Old Chair, Clinical Investigation,
Director, Parker Institute for Cancer Immunotherapy,
Memorial Sloan Kettering, Associate Director, Ludwig Center for Cancer Immunotherapy, Professor of Medicine, Weill Medical College of Cornell University, USA

Dr. Rakesh K. Jain
Ph.D., A. W. Cook Professor of Radiation Oncology (Tumor Biology), Director, E.L. Steele Laboratories
Department of Radiation Oncology
Harvard Medical School and
Massachusetts General Hospital
Boston, USA

Dr. Solange Peters
Head of the Medical Oncology Department,
Head of the Specialized Consultation for Thoracic Tumors,
Physician in charge of the Center for thoracic tumors
University of Lausanne,
Switzerland

Dr. John B. Haanen
Head of the Division of Medical Oncology and Staff Scientist, Division of Immunology,
Professor of Translational Immunotherapy of Cancer,
Leiden University Medical Centre,
The Netherlands

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INVITED INTERNATIONAL FACULTY

Dr. Olivera J. Finn
Chair and Professor, Department of Immunology,
University of Pittsburgh School of Medicine,
Director of the Immunology Program,
University of Pittsburgh Cancer Institute,
USA

Dr. Padmanee Sharma
Professor,
Department of Genitourinary Medical Oncology,
Professor,Department of immune-Oncology,
Division of Cancer Medicine,
The University of Texas MD Anderson Cancer Center,
USA

Dr. Sherene Loi
MMBS (Hons), FRACP, PhD, FAHMS
Professor, Cancer Therapeutics
Head, Translational Breast Cancer Genomics and Therapeutics Lab, Peter MacCallum Cancer Centre
University of Melbourne, Melbourne, Australia

Prof. Silvia Stacchiotti
Department of Medical Oncology
IRCCS Foundation,National Cancer Institute,
Milan, Italy

Dr. David Gottlieb
Professor of Haematology
University of Sydney
Program Director BMT, Head Cell Therapies,
Westmead Hospital Sydney,
Sydney

Prof. Laura Locati
Head and Neck Unit
Depart of Medical Oncology
IRCCS Foundation, National Cancer Institute,
Milan, Italy

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INVITED INTERNATIONAL FACULTY

Dr. Ravindran Kanesvaran
Deputy Head & Senior Consultant,
Division of Medical Oncology,
National Cancer Centre,
Singapore

Dr. Aung Naing
Professor,
Department of Investigational Cancer Therapeutics,
Division of Cancer Medicine, The University of Texas
MD Anderson Cancer Center,
USA

Dr. Naval G. Daver
Associate Professor,
Department of Leukemia,
MD Anderson Cancer Center,
USA

Dr. Aditi Shastri
Assistant Professor of Oncology,
Division of Hematologic Malignancies & Bone Marrow Transplant,
Montefiore Medical Center & Albert Einstein College of Medicine, Bronx, New York, USA

Dr. Nirali N. Shah
M.D., M.H.Sc.
Investigator, Pediatric Oncology Branch,
NIH Lasker Clinical Research Scholar,
NIH Distinguished Scholar Head,
Hematologic Malignancies Section,
Center for Cancer Research, National Cancer Institute
USA

Dr. Boro Dropulic
Chief Science Officer
Lentigen Technology, Inc.
USA

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LIVE I-OSI Virtual Congress

SCIENTIFIC PROGRAM | FRIDAY 30TH OCTOBER, DAY 1	
15:30 - 16:10	**Conference Inauguration** **Dr. R. A. Badwe, Dr. Shubhada Chiplunkar, Dr. Jyoti Bajpai, Dr. Sudeep Gupta, Dr. S. D. Banavali, Dr. C. S. Pramesh Dr. Hemant Malhotra, Dr. Kumar Prabhash** **Announcement for "Sprinkles Cancer Care Foundation"**
	Chairpersons : Dr. Anil D'Cruz, Dr. Sadashivudu Gundeti
	Session Italy Time:- 11:40 - 12:20
16:10 - 16:15	**Session introduction**
16:15 - 16:40	**Immunotherapy in Head and Neck cancers : Investing in knowledge paying the best dividends** **Speaker :** Dr. Laura Locati
16:40 - 16:50	**Q & A** **Lead Discussant :** Dr. Vanita Noronha
	Chairpersons : Dr. Rajiv Sarin, Dr. Vinay Deshmane
	Session Australia Time:- 22:20 - 23:00
16:50 - 16:55	**Session introduction**
16:55 - 17:20	**Immunotherapy of Breast cancers : Facts can beat anything you fancy** **Speaker :** Dr. Sherene Loi
17:20 - 17:30	**Q & A** **Lead Discussant :** Dr. Sudeep Gupta
	Chairpersons : Dr. Asha Kapadia, Dr. Jaya Ghosh
	Session USA Time:- 07:00 - 07:40
17:30 - 17:35	**Session introduction**
17:35 - 18:00	**Strategies for improving management of immune related adverse events** **Speaker :** Dr. Aung Naing
18:00 - 18:10	**Q & A** **Lead Discussant :** Dr. Sewanti Limaye
	Chairpersons : Dr. D. C. Doval, Dr. Vinod Raina
	Session Netherlands Time:- 13:40 - 14:20
18:10 - 18:15	**Session introduction**

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SCIENTIFIC PROGRAM | FRIDAY 30TH OCTOBER, DAY 1	
18:15 - 18:40	**Mitigating checkpoint inhibitors toxicities** **Speaker :** Dr. John B. Haanen
18:40 - 18:50	**Q & A** **Lead Discussant :** Dr. Atul Sharma
	Chairpersons : Dr. Shubhada Chiplunkar, Dr. Girdhari Lal
	Session USA Time:- 09:20 - 10:00
18:50 - 18:55	**Session introduction**
18:55 - 19:20	**Vaccines for the prevention of human non-viral cancers** **Speaker :** Dr. Olivera J. Finn
19:20 - 19:30	**Q & A** **Lead Discussant :** Dr. Shyam Aggarwal
	Chairpersons : Dr. Avnish Saklani, Dr. Vineet Talwar, Dr. S. D. Banavali
	Session USA:- 10:00 -11:00
19:30 - 19:35	**Session introduction**
19:35 - 20:20	**Oration - Checkpoint Blockade Therapy : Focusing on Combinations to Improve Outcomes** **Speaker :** Dr. Jedd Wolchok
20:20 - 20:30	**Q & A** **Lead Discussant :** Dr. T. Raja
	Chairpersons : Dr. Ramesh Nimmagadda, Dr. Padmaj Kulkarni
	Italy Time:- 16:00 - 16:45
20:30 - 21:15	**Panel discussion : Check point inhibitors in solid tumors: Practical applications of guidelines in Indian context** **Moderator :** Dr. Senthil Rajappa Panelist : Dr. Laura Locati, Dr. B. K. Smruti, Dr. Amit Rauthan, Dr. T.P. Sahoo, Dr. Ullas Batra, Dr. Amit Joshi, Dr. Shona Nag, Dr. Bhawna Sirohi, Dr. Amit Agarwal
21:15 - 21:20	**Important announcements**

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SCIENTIFIC PROGRAM | SATURDAY 31ST OCTOBER, DAY 2	
	Chairpersons : Dr. C.S. Pramesh, Dr. J.P. Agarwal
	Session Switzerland Time:- 12:40 - 13:20
16:10 - 16:15	**Session introduction**
16:15 - 16:40	**Breakthroughs in Lung Cancer Immunotherapy : The Story of Fiction in Medicine** **Speaker :** Dr. Solange Peters
16:40 - 16:50	**Q & A** **Lead Discussant :** Dr. Navneet Singh
	Chairpersons : Dr. Siddharth Laskar, Dr. Bharat Rekhi
	Session Italy Time:- 12:20 - 13:00
16:50 - 16:55	**Session introduction**
16:55 - 17:20	**Immunotherapy of Sarcoma : Amusing the patients or / and Curing the disease** **Speaker :** Prof. Silvia Stacchiotti
17:20 - 17:30	**Q & A** **Lead Discussant :** Dr. Chirag Desai
	Chairpersons : Dr. Raghunadarao D., Dr. Jyoti Wadhwa
	Session Singapore Time:- 20:00 - 20:40
17:30 - 17:35	**Session introduction**
17:35 - 18:00	**Immunotherapy in rare and challenging situations (Extreme of ages, comorbidities, immunocompromised and autoimmune conditions)** **Speaker :** Dr. Ravindran Kanesvaran
18:00 - 18:10	**Q & A** **Lead Discussant :** Dr. G.S. Bhattacharya
	Chairpersons : Dr. Moni Abraham Kuriakose, Dr. Navin Khattry
	Session USA Time:- 07:40 - 08:20
18:10 - 18:15	**Session introduction**
18:15 - 18:40	**From the Clinic to the Lab : Evaluating Mechanisms of Response and Resistance to Immune Checkpoint Therapy** **Speaker :** Dr. Padmanee Sharma

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SCIENTIFIC PROGRAM | SATURDAY 31ST OCTOBER, DAY 2	
18:40 - 18:50	**Q & A** **Lead Discussant :** Dr. Nitesh Rohatgi
	Chairpersons : Dr. Amit Awasthi, Dr. Dipankar Nandi
	Session USA Time:- 09:20 - 10:00
18:50 - 18:55	**Session introduction**
18:55 - 19:20	**Normalizing the tumor microenvironment to improve immunotherapy of cancer : Bench to Bedside** **Speaker :** Dr. Rakesh K. Jain
19:20 - 19:30	**Q & A** **Lead Discussant :** Dr. S.D. Banavali
	Chairpersons : Dr. Sudeep Gupta, Dr. Govind Babu, Dr. Jyoti Bajpai
	Session USA Time:- 09:00 - 10:00
19:30 - 19:35	**Session introduction**
19:35 - 20:20	**Oration - Immune Checkpoint Blockade in Cancer Therapy : New insights into therapeutic mechanisms** **Speaker :** Dr. James P. Allison
20:20 - 20:30	**Q & A** **Lead Discussant :** Dr. Kumar Prabhash
	Chairpersons : Dr. S.H. Advani, Dr. Bhavna Parikh
	Singapore Time:- 23:00 - 23:45 **Italy time:- 16:00 - 16:45** **Switzerland time:- 17:00 - 17:45** **USA time:- 10:00 - 10:45**
20:30 - 21:15	**Panel discussion : Optimal management of Rare Diseases & Situations in clinics** **Moderator :** Dr. Jyoti Bajpai Panelist : Dr. Silvia Stacchiotti, Dr. Solange Peters, Dr. Ravindran Kanesvaran, Dr. Aung Naing, Ms. Nishu Goel, Dr. Rakesh Jalali, Dr. Bharath Rangarajan, Dr. Amish Vora
21:15 - 21:20	**Important announcements**

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SCIENTIFIC PROGRAM | SUNDAY 1ST NOVEMBER, DAY 3	
	Chairpersons : Dr. Maheboob Basade, Dr. Vikram Mathews
	Session USA Time:- 23:30 - 00:10
09:00 – 09:05	**Session introduction**
09:05 – 09:30	**Nuances in Automated and Decentralized CAR-T Cell Manufacture** **Speaker :** Dr. Boro Dropulic
09:30 – 09:40	**Q & A** **Lead Discussant :** Dr. Chetan Dhamne
	Chairpersons : Dr. Anita Ramesh, Dr. Reetu Jain
	Session USA Time:- 23:10 - 23:50
09:40 - 09:45	**Session introduction**
09:45 - 10:10	**Immunotherapy (Antibodies (ADCs and BiTEs), checkpoint inhibitors, CD47) in hematological malignancies** **Speaker :** Dr. Naval G. Daver
10:10 - 10:20	**Q & A** **Lead Discussant :** Dr. Hemant Malhotra
	Chairpersons: Dr. Purna Kurkure, Dr. Pankaj Malhotra
	Session USA Time:- 00:50 - 01:30
10:20 - 10:25	**Session introduction**
10:25 - 10:50	**CAR-T Cells : Beyond CD19** **Speaker :** Dr. Nirali Shah
10:50 - 11:00	**Q & A** **Lead Discussant :** Dr. (Surg Cdr) Gaurav Narula
11:00 - 11:25	**Session USA Time:- 01:30 - 02:20** **CAR-T cell therapy in rare and challenging situations (Extreme of ages, comorbidities, CNS disease)** **Speaker :** Dr. Aditi Shastri

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SCIENTIFIC PROGRAM | SUNDAY 1ST NOVEMBER, DAY 3	
	Chairpersons: Dr. Purvish Parikh, Dr. Sunil Arora
11:25 - 11:30	Session Introduction
11:30 - 11.45	**CAR-T cell therapy : Indian context** **Speaker :** Dr. Rahul Purwar
11:45 - 11:55	**Q & A** **Lead Discussant :** Dr. Vivek Radhakrishnan
	Chairpersons : Dr. Tapan Saikia, Dr. Lalit Kumar
	Session Sydney Time:- 17:25 - 18:05
11:55 - 12:00	**Session introduction**
12:00 - 12:25	**Applications of adoptive immunotherapy following intensive therapy in oncology** **Speaker :** Dr. David Gottlieb
12:25 – 12:35	**Q & A** **Lead Discussant :** Prashant Mehta
	Chairpersons : Dr. Prakash Chitalkar, Dr. Soumen Basak
12:35 - 13:15	**Panel discussion : Immunotherapy in haematolymphoid malignancies - Its potential and future promise** **Moderator :** Dr. Manju Sengar Pannelist : Dr. Ashish Bakshi, Dr. Rahul Purwar, Dr. Hari Menon, Dr. Sameer Bakhshi, Dr. Hasmukh Jain, Dr. Vipul Sheth, Dr. Abhay Bhave, Dr. Lingaraj Nayak
13:15 - 13:25	**Indian Data Presentation** **National Centres :** Dr. George Abraham
13:25 – 13:35	**Vote of thanks : Organizing Committee**

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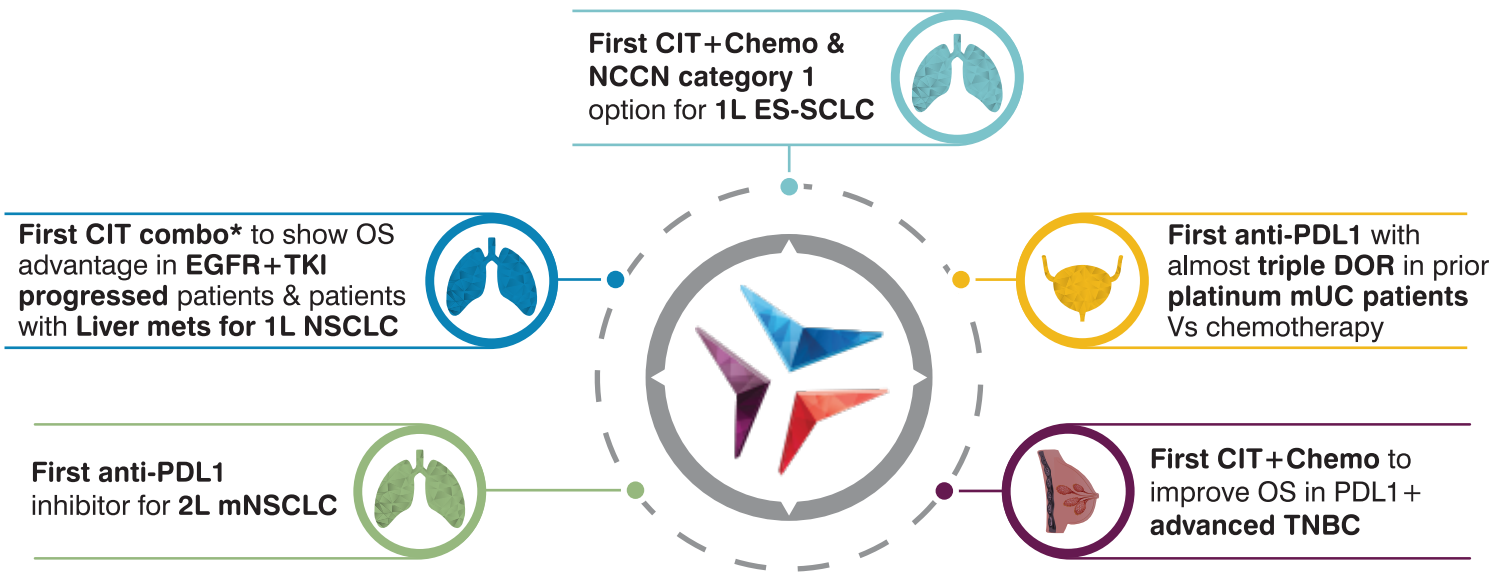

OS ADVANTAGE OF ATEZOLIZUMAB IN PHASE III STUDIES OF NSCLC, ES-SCLC, UC AND TNBC

	Study, Therapy line (Therapy Arm)	Population	HR (95 % CI)	HR (95 % CI)	Median OS, Months A-Arm	Median OS, Months Control.-Arm
NSCLC	**IMpower150[1], 1L** (A + Bev + Carbo + P vs. Bev + Carbo + P)	**ITT-WT[b]** (N = 696)		**0.78[a]** (0.64–0.96)	19.2	14.7
NSCLC	**OAK[2], 2L** (A mono vs. Doc)	**ITT** (N = 850)		**0.73** (0.62–0.87)	13.8	9.6
ES-SCLC	**IMpower133[3], 1L** (A + Carbo + E vs. Plac + Carbo + E)	**ITT** (N = 403)		**0.70** (0.54–0.91)	12.3	10.3
	IMvigor211[4], 2L (A mono vs. Vin/P/Doc)	**ITT** (N = 931)		**0.85[a]** (0.73–0.99)	8.6	8.0
	IMpassion130[5], 1L (A + nab-P vs. Plac + nab-P)	**PD-L1 IC+** (N = 369)		**0.71[a, b]** (0.54–0.93)	25.0[§]	18.0

0,3 Advantage A-Arm ← 1 → Advantage Control -Arm

§ The IMpassion130 study did not reach the co-primary endpoint of a significant improvement in median overall survival (mOS) in the ITT population in the interim analysis. The mOS in the PD-L1 IC-positive study population failed therefore not formally tested.

a Stratified. b Cannot be formally determined based on the pre-specified hierarchical analysis plan.

1L = 1st line therapy; 2L = 2nd line therapy; A = Atezolizumab; Bev = Bevacizumab; Carbo = Carboplatin; CI = Confidence interval; Cis = Cisplatin; Doc = Docetaxel; E = Etoposide; ES-SCLC = "Extensive-stage" small cell lung cancer; Gem = Gemcitabine; HCC = Hepatocellular carcinoma; HR = Hazard ratio; IC = Tumor infiltrating immune cell; ITT = Intention-to-treat; NE = Not reached; NSCLC = Non-small cell lung cancer; OS = Overall survival; P = Paclitaxel; Pem = Pemetrexed; Plac = Placebo; S = Sorafenib; TC = Tumor cell; TNBC = Triple negative breast cancer; UC = Urothelial carcinoma; Vin = Vinflunin; WT = Wild type.

References:
1. Socinski MA et al. N Engl J Med 2018; 378: 2288-2301. 2. Rittmeyer A et al. Lancet 2017; 389: 255-265. 3. Liu SV et al. WCLC 2018; Abstract No. PL02.07. 4. Powles T et al. N Engl J Med 2018; 391: 748-751. 5. Schmid P et al. ASCO 2019; Abstract No. 1003.

PDL1 - Programed Death Ligand 1
NSCLC - Non-small Cell Lung Cancer
CIT - Cancer Immunotherapy
CIT combo* - Atezolizumab + Bevacizumab + Carboplatin + Paclitaxel
EFGR - Epidermal Growth Factor Receptor, TKI - Tyrosine Kinase Inhibitor
NCCN - National Comprehensive Cancer Network
ES-SCLC - Extensive Stage Small Cell Lung Cancer
DOR - Duration of Response
mUC- Metastatic Urothelial Cancer
TNBC - Triple Negative Breast Cancer

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ABRIDGED PRESCRIBING INFORMATION
Atezolizumab Injection (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 1,200 mg atezolizumab. **Indications: Urothelial carcinoma:** 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:** Tecentriq is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. 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. **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 tumors have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease. **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. **Tecentriq monotherapy** 2L NSCLC, 1L/2L UC. The recommended dose of Tecentriq is 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 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. 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. **Duration of Treatment:** Patients are treated with Tecentriq until loss of clinical benefit or unacceptable toxicity. 1L TNBC **Delayed or Missed Doses:** If a planned dose of Tecentriq is missed, it should be administered as soon as possible; do not wait until the next planned dose. The schedule of administration should be adjusted to maintain the appropriate interval between doses. **Dose Modifications:** No dose reductions of Tecentriq are recommended. **Pediatric use:** The safety and efficacy of Tecentriq in children and adolescents below 18 years of age have not been established. **Contraindications:** Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. **Warnings and Precautions: Immune-related pneumonitis:** Cases of pneumonitis, including fatal cases, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be withheld for Grade 2 pneumonitis, and treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treatment with Tecentriq should be permanently discontinued for Grade 3 or 4 pneumonitis. **Immune-related hepatitis:** Cases of hepatitis, some leading to fatal outcomes, have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be withheld for Grade 2 hepatitis and treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treatment with Tecentriq should be permanently discontinued for Grade 3 or Grade 4 events. **Immune-related colitis:** Cases of diarrhea or colitis have been observed in clinical trials with Tecentriq. Treatment with Tecentriq should be withheld for Grade 2 or 3 diarrhea. For Grade 2 diarrhea or colitis, treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treat Grade 3 diarrhea or colitis, initiate IV corticosteroids as in Grade 2, and convert to oral corticosteroids after improvement. Treatment with Tecentriq should be permanently discontinued for Grade 4 diarrhea or colitis. **Immune-related endocrinopathies:** Hypothyroidism, hyperthyroidism, adrenal insufficiency and type 1 diabetes mellitus, including diabetic ketoacidosis, have been observed in clinical trials with Tecentriq. For symptomatic hypothyroidism, Tecentriq should be withheld and Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable. Treatment with thyroid hormone replacement should be initiated as needed. For symptomatic hyperthyroidism, Tecentriq should be withheld and Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable. Treatment with anti-thyroid therapy should be initiated as needed. For symptomatic adrenal insufficiency, Tecentriq should be withheld and Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treatment with Tecentriq should be withheld for Grade 2 or Grade 3 hypophysitis and Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. For Grade 4 Hypophysitis, treatment with Tecentriq should be permanently discontinued. Tecentriq should be withheld and Treatment with insulin should be initiated for type 1 diabetes mellitus in case of ≥ Grade 3 hyperglycemia (fasting glucose >250 mg/dL), Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable. **Immune-related meningoencephalitis and neuropathies:** Meningoencephalitis has been observed in clinical trials with Tecentriq. Patients should be monitored for clinical signs and symptoms of meningitis or encephalitis. Myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome, which may be life threatening, were observed in patients receiving Tecentriq. Patients should be monitored for symptoms of motor and sensory neuropathy. Treatment with Tecentriq should be permanently discontinued for all grades of Meningitis, encephalitis, myasthenic syndrome /myasthenia gravis, Guillain-Barré syndrome. **Immune-related pancreatitis:** Pancreatitis, including increases in serum amylase and lipase levels, has been observed in clinical trials with Tecentriq. Patients should be closely monitored for signs and symptoms that are suggestive of acute pancreatitis. Treatment with Tecentriq should be withheld for Grade 2 or 3 pancreatitis (≥ Grade 3 serum amylase or lipase levels increased [>2.0 ULN]). Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treatment with Tecentriq should be permanently discontinued for Grade 4, or any grade of recurrent pancreatitis. **Immune-related myocarditis:** has been observed in clinical trials with Tecentriq. Tecentriq should be withheld for Grade 2 myocarditis and permanently discontinued for Grade 3 or 4 myocarditis. **Immune-related myositis:** Treatment with Tecentriq should be withheld for Grade 2 or Grade 3 myositis and treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. Treatment with Tecentriq should be permanently discontinued for Grade 3 recurrent myositis or Grade 4 events. **Immune-related nephritis:** Nephritis has been observed in clinical trials with Tecentriq. For grade 2 nephritis, Tecentriq should be withheld and treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤10 mg/day oral prednisone or equivalent. 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. For, Grade 1 or 2 infusion related reactions, the rate of infusion should be reduced or treatment should be withheld and premedication with antipyretic and antihistamines may be considered for subsequent doses. Tecentriq should be permanently discontinued in patients with Grade 3 or 4 infusion related reactions. **Rash:** For Grade 3 rash, the treatment with Tecentriq should be withheld. For Grade 4, the 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. **General Disorders:** Peripheral Edema of all grades is very common adverse drug reaction when Tecentriq is used as a part of combination therapy treatment. **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. Tecentriq is 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:** It is not known whether Tecentriq is excreted in human breast milk. No studies have been conducted to assess the impact of Tecentriq on milk production or its presence in breast milk. As the potential for harm to the nursing infant is unknown, a decision must be made to either discontinue breast-feeding or discontinue Tecentriq therapy. **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. **Side Effects:** The most commonly reported AEs with Tecentriq in monotherapy includes fatigue, decreased appetite, cough, nausea, dyspnea, constipation, diarrhea, pyrexia, vomiting, arthralgia, back pain, urinary tract infection, asthenia, anemia, pruritus, rash, headache, and in case of combination therapy it includes anemia, neutropenia, thrombocytopenia, leukopenia, hypothyroidism, constipation, headache, lung infection, hypomagnesemia, dizziness, peripheral neuropathy, alopecia, hypertension. **Post marketing** – No new adverse drug reactions have been identified from postmarketing experience. **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 medicine 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. **DESCRIPTION:** Atezolizumab is a programmed cell death ligand 1 (PD-L1) blocking antibody. Atezolizumab is an Fc-engineered, humanized, non-glycosylated IgG1 kappa immunoglobulin that has a calculated molecular mass of 145 kDa. **Shelf-life:** 3 Years for Atezolizumab Injection 1200mg/20ml and 2 Years for Atezolizumab Injection 840mg/14ml **Packs:** Each pack contains: • A single-use vial of 20ml containing 1200mg of atezolizumab (60mg/ml). • A single-use vial of 14ml containing 840mg of atezolizumab (60mg/ml). Please read full prescribing information before usage.

DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE
IMP-063/2017 Dated 31 March 2017

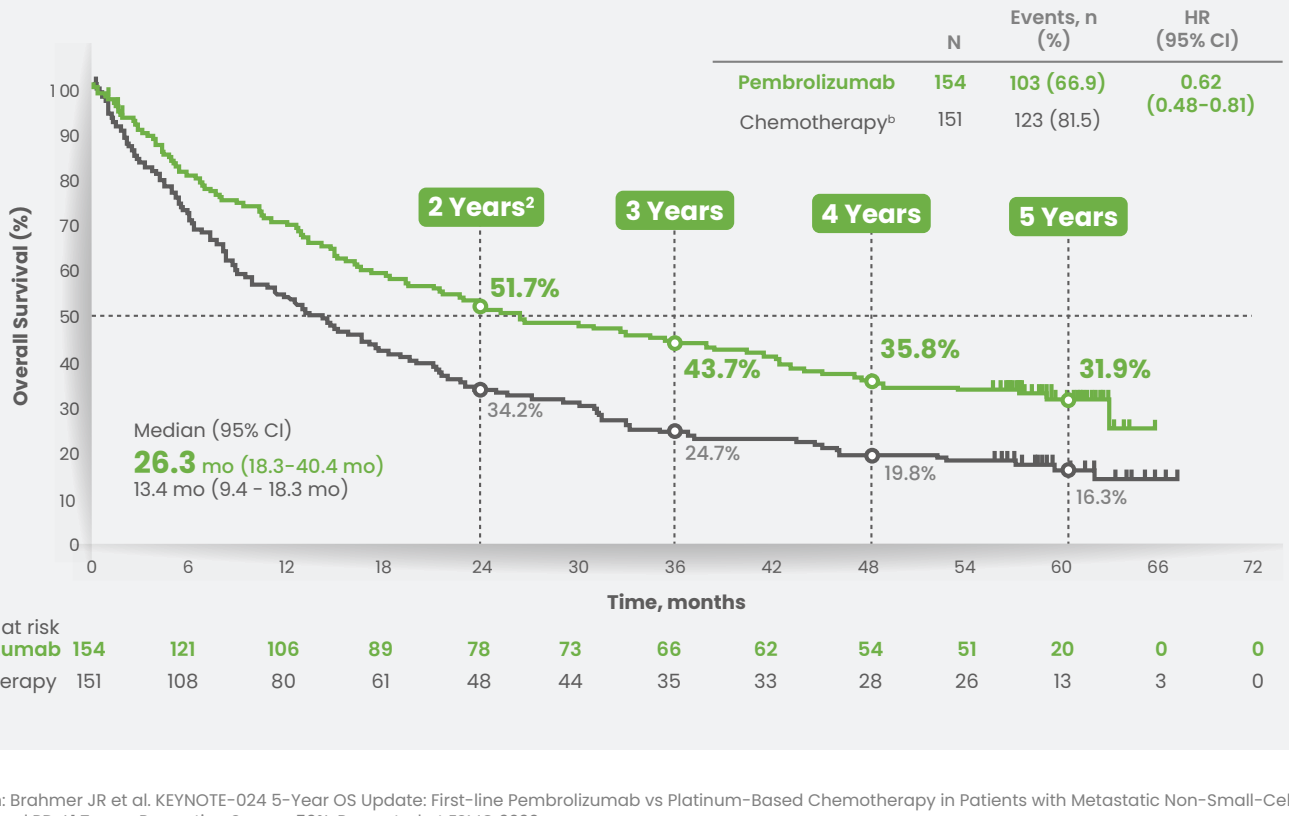
DATE OF REVISION
Current at April 2020, Version13.0

PM-IN-0560

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYNOTE-024: 5-year OS Analysis[a,1]

KEYTRUDA® approximately Doubles 5-Years OS rate despite of 66% effective crossover rate[a]



	N	Events, n (%)	HR (95% CI)
Pembrolizumab	154	103 (66.9)	0.62 (0.48-0.81)
Chemotherapy[b]	151	123 (81.5)	

No. at risk													
Pembrolizumab	154	121	106	89	78	73	66	62	54	51	20	0	0
Chemotherapy	151	108	80	61	48	44	35	33	28	26	13	3	0

References:

1. Adapted from: Brahmer JR et al. KEYNOTE-024 5-Year OS Update: First-line Pembrolizumab vs Platinum-Based Chemotherapy in Patients with Metastatic Non-Small-Cell Lung Cancer and PD-L1 Tumor Proportion Score ≥ 50%. Presented at ESMO 2020.
2. Adopted on 25/11/2019 from KEYNOTE 024 3 year survival update: Pembrolizumab Versus Platinum Based Chemotherapy for Advanced NSCLC; Reck KN024 WCLC 2019.

OS: Overall Survival; HR: Hazard Ratio; CI: Confidence Interval; mo: Months; PFS: Progression-Free Survival; ORR: Overall Response Rate; DoR: Duration of Response; RECIST: Response Evaluation Criteria in Solid Tumors; ECOG: Eastern Cooperative Oncology Group

Study Design
Brahmer et al 2020
KEYNOTE-024 was a 5-year follow-up study. Eligible patients were randomized to receive Pembrolizumab (KEYTRUDA®) (200 mg Q3W for up to 35 cycles [~2 years]) or chemotherapy. Randomization was stratified by ECOG PS (0/1), histology (squamous/nonsquamous), and region (East Asia/other). For second-course, patients were randomized to receive Pembrolizumab (KEYTRUDA®) (200 mg Q3W for up to 17 cycles [1 year] in patients who completed 2 years of therapy or who stopped Pembrolizumab (KEYTRUDA®) after achieving CR and then had PD were eligible for a second course of Pembrolizumab (KEYTRUDA®) monotherapy. Patients were randomized to receive chemotherapy who had PD and met eligibility criteria could cross over to Pembrolizumab (KEYTRUDA®) monotherapy. Endpoints included PFS (primary); OS, ORR, and safety (secondary); and DoR (exploratory). For this analysis, response/PD was assessed by investigators per RECIST v1.1.

KEYNOTE-024 3-Year Survival Update
Patients were randomized to Pembrolizumab (KEYTRUDA®) 200 mg for 2 years or platinum doublet 4- to 6- cycles plus optional maintenance (nonsquamous), with stratification by ECOG score of 0 or 1, tumor histology (squamous/nonsquamous), and region (East Asia/non-East Asia). Patients in the chemotherapy arm could cross over to Pembrolizumab (KEYTRUDA®) upon disease progression if they met eligibility criteria. PFS was the primary endpoint and OS was key secondary endpoint.

[a] ITT population.
[b] Effective crossover rate from chemotherapy to anti-PD-(L)1 therapy, 66.0% (99 patients in total crossed over to anti-PD-[L]1 therapy: 83 patients crossed over to pembrolizumab during the study, and 16 patients received subsequent anti-PD-[L]1 therapy outside of crossover, patients may have received > 1 subsequent anti-PD-[L]1 therapy). Data cutoff; June 1, 2020.

KEYTRUDA® first EVIDENCE MATTERS

Abridged Prescribing Information
KEYTRUDA®

[Pembrolizumab 100 mg/4 mL (25 mg/mL) Injection]

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®. **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: • 200 mg for NSCLC that has not been previously treated with chemotherapy; • 2 mg/kg for NSCLC that has been previously treated with chemotherapy or for melanoma. Patients should be treated with KEYTRUDA® until disease progression or unacceptable toxicity. **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 06/20 Effective date of ABPI - 4th Aug, 2020

AE Reporting

Greeting from MSD Pharmaceuticals, Pvt Ltd

To report Adverse Events (AEs) related to our products, please contact :

Mode of reporting the adverse event	***Details***
Fax	*0124-4375562*
Toll Free Number	*18001032642*
E-mail	*pharmacovigilance.india@merck.com*
Postal Address	*Global 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.

Before prescribing KEYTRUDA®, please read the full Prescribing Information.

For the use only of registered medical practitioners

MSD INVENTING FOR LIFE
MSD Oncology

MSD Pharmaceuticals Pvt. Ltd.
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IN-KEY-00321 - 21/10/2020 - 14/10/2021

KEYTRUDA® first EVIDENCE MATTERS

Immuno-Oncology

For patients with recurrent or metastatic SCCHN after platinum-based therapy,

START EARLY with OPDYTA®

as your preferred monotherapy post-platinum

IN THE LAD OR R/M SETTING[#1]:

If your patient receives a **platinum-based therapy**[†] and progresses...

OPDYTA® (nivolumab)

OPDYTA® as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell carcinoma of the head & neck after platinum – based therapy[2]

LAD: Locally Advanced Disease; R/M SCCHN: Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

Based on Checkmate 141 eligibility criteria.

† Therapy administered in the following treatment settings: locally advanced disease (LAD) (neoadjuvant/induction, adjuvant, and primary [unresectable locally advanced] settings) and de novo metastatic.

1. Gillison ML, Blumenschein G Jr, Fayette J, et al. CheckMate 141: 1-year update and subgroup analysis of nivolumab as first-line therapy in patients with recurrent/metastatic head and neck cancer. Oncologist. 2018;23(9):1079-1082.

2. Opdyta Prescribing Information Version 6.3 dated 23-Apr-2019.

Immuno-Oncology

OPDYTA® (nivolumab)

EXPECT MORE.
DO MORE.

NOW
APPROVED IN 9 INDICATIONS[2]

Give MORE patients the OPDYTA® opportunity!

Ref. 2. Opdyta Prescribing Information Version 6.3 dated 23-Apr-2019.

Abridged Prescribing Information (API)
For the use of an oncologist or a hospital or a laboratory 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. **Indications:** NSCLC: As a single agent for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy; RCC: As a single agent for the treatment of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults; SCCHN: As monotherapy for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck 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 classical Hodgkin lymphoma (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 hepatocellular carcinoma (HCC) who have been previously treated with sorafenib; Urothelial Carcinoma (UC): For the treatment of patients with locally advanced or metastatic urothelial carcinoma 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 colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. **Dosage and administration:** 3 mg/kg administered intravenously every 2 weeks over 60 minutes. **Contraindications:** None. **Warnings and Precautions:** Immune related pneumonitis: Withhold for grade 2 and permanently discontinue for grade 3 or 4 pneumonitis. Immune-related colitis: Withhold for grade 2 or 3 and permanently discontinue for grade 4 diarrhoea or colitis. Immune-related hepatitis: Monitor for changes in liver function. Withhold for grade 2 and permanently discontinue for grade 3 or 4 transaminase or total bilirubin elevation. Immune-related nephritis and renal dysfunction: Monitor for changes in renal function. Withhold for grade 2 or 3 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 hypophysitis. 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. Solid organ transplant rejection and graft-versus-host-disease (GVHD) in prior allogeneic stem cell transplant patients who subsequently received nivolumab, have been reported. Complications of allogeneic hematopoietic stem cell transplant (HSCT) after nivolumab: Monitor for transplant-related complications, including GVHD. Transplantrelated mortality has occurred. Infusion reactions: Discontinue for severe and lifethreatening infusion reactions. Patients with mild or moderate infusion reaction may receive nivolumab with close monitoring and use of premedication according to local treatment guidelines. 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 metabolising 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 effectiveness 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 severe (total bilirubin >3 times ULN and any AST) hepatic impairment. **Renal Impairment:** The safety and efficacy of nivolumab have not been studied in patients with severe 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 6.3, dated 23-Apr-2019. Issued – 23-Apr-2019. **Before prescribing, consult full prescribing information. For further information, please contact:** Bristol-Myers Squibb India Pvt. Ltd., 6th floor, Tower 1, The Indiabulls Finance Centre Senapati Bapat Marg, Elphinstone (W), Mumbai - 400 013, India. Telephone: +91 22 6628 8600

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