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5th Annual Review on Head & Neck Cancers

5th, 6th & 7th August, 2022

Organizing Chairpersons

Dr. B. K. Smruti

Dr. Vijay Haribhakti

Dr. Kumar Prabhash

Organizing Secretaries

Dr. Mandar Deshpande

Dr. Sewanti Limaye

Dr. Kaustav Talapatra

Dr. Prasad Dandekar

Scientific Committee Chair

Dr. Vanita Noronha

Dr. Vijay Patil



Venue

Courtyard by Marriott,
Mumbai

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5th Annual Review on Head & Neck Cancers

5th, 6th & 7th August, 2022

Welcome Address

On behalf of the organizing committee and Mumbai Oncology Association, we are pleased to invite you to the **"5th Annual Review on Head and Neck Cancers Conference"**. This will be a hybrid conference and will be held on **05 (Virtual), 06 & 07 (Hybrid) August 2022**

The 5th Annual Review on Head and Neck Cancers Conference 2022 will provide practitioners an update in head and neck cancers with a comprehensive overview of the current standard of care practices as well as review of evolving and innovative treatment approaches. Management recommendations are rapidly evolving in this era of immune oncology and will receive particular attention, including a discussion of de-escalation and the current randomised trials evaluating de-escalation protocols.

The focus of this conference will be on latest in multidisciplinary approach to head and neck treatment, novel treatment breakthroughs and leading research publications and current best practices in supportive and survivorship care.

Distinguished faculty from Mumbai as well as from prominent National faculty will present a series of recent important publications followed by open panels which cover the management of malignancies in critical subsites within the head and neck such as the oral cavity, oropharynx, larynx, thyroid, and others. We will also cover important publications on rare subjects in head and neck cancers.

Open interaction between faculty and participants will be encouraged throughout the sessions. Participants are encouraged to pre-submit important problem statements needing Indian consensus.

We look forward to your active participation.

Regards

Organising Team

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5th Annual Review on Head & Neck Cancers

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5th August 2022

Day 1 (Virtual Hall A)

6:30 pm - 7:00 pm

Role of LBx in H&N Cancers

Speaker : Dr. Avik Mukherjee

7.00 pm - 7.30 pm

Rationale of PD-L 1 CPS as predictive biomarker
in HNSCC (Supported by MSD)

Speaker : Dr. Nandini Menon

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6th August 2022

Day 2 Hybrid

08.00 am - 09.00 am

Registration

09.00 am - 10.25 am

Session 1: Key Publication On Oral Cancer

09.00 am - 09.10 am

**Chairpersons : Dr. S. K. Shrivastava
Dr. Deepak Parikh**

Reviewer : Dr. Ajaykumar Singh

- Phase 3 randomized study comparing docetaxel-platinum with docetaxel-platinum-5 fluorouracil as neoadjuvant chemotherapy in technically unresectable oral cancer

Author : Ajaykumar Singh

Citation : Journal of Clinical Oncology 2022
40:16_suppl, 6013-6013

- Intensifying adjuvant therapy in advanced oral cavity carcinoma: Result of randomized study

Author: Sarbani Ghos Laskar

Citation: Green journal-Radiotherapy & Oncology

09.10 am - 09.20 am

Reviewer : Dr. H. Yathiraj Prahlad

- Results from a prospective, randomised study on (accelerated) preoperative versus (conventional) postoperative radiotherapy in treatment of patients with resectable squamous cell carcinoma of the oral cavity – The ARTSCAN 2 study

Author : Johan Wennerberg

Citation : Radiother Oncol. 2022 Jan;166:26-32

- Neoadjuvant Chemoradiotherapy for Oral Cavity Cancer: Predictive Factors for Response and Interim Analysis of the Prospective INVERT-Trial

Author : Jens von der Grün

Citation : Front Oncol. 2022; 12: 817692

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09.20 am - 09.30 am

Reviewer : Dr. Shilpi Sharma

- Prospective Phase II Open-Label Randomized Controlled Trial to Compare Mandibular Preservation in Upfront Surgery with Neoadjuvant Chemotherapy Followed by Surgery in Operable Oral Cavity Cancer

Author : Devendra Chaukar

Citation : Journal of Clinical Oncology 40, no. 3 (January 20, 2022) 272-281

- Effect of elective neck dissection versus sentinel lymph node biopsy on shoulder morbidity and health-related quality of life in patients with oral cavity cancer: A longitudinal comparative cohort study

Author: Gerben van Hinte

Citation: Oral Oncol. 2021 Nov;122:105510

09.30 am - 09.40 am

Reviewer : Dr. Nikhil Dharmadhikari

- Hyperbaric oxygen treatment of mandibular osteoradionecrosis: Combined data from the two randomized clinical trials DAHANCA-21 and NWHHT2009-1

Author : Lone E Forner

Citation : Radiother Oncol. 2022 Jan;166:137-144

- Transoral robotic surgery with neck dissection versus nonsurgical treatment in stage I and II human papillomavirus-negative oropharyngeal cancer

Author : Bollig CA

Citation : Head Neck. 2022 Jul;44(7):1545-1553. doi: 10.1002/hed.27045

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09.40 am - 09.50 am

Reviewer : Dr. Pritam Kataria

- Effectiveness of adjuvant chemoradiotherapy for oral cavity squamous cell carcinoma with minor and major extranodal extension: A multi-institutional consortium study
Author : Mirko Manojlovic Kolarski
Citation : Journal of Clinical Oncology 2022 40:16_suppl, 6010-6010
- Prognostic Value of Lymph Node Density in Node-Positive Oral Squamous Cell Carcinoma
Author: Amol Padegaonkar
Citation: Indian Journal of Surgical Oncology (2021)

09.50 am - 10.20 am

**Chairpersons : Dr. Prakash Ramachandra
Dr. Vicky Khattar**

- Panel Discussion On Oral Cancer
Moderator : Dr. Arvind Krishnamurthy
Panelists : Dr. Amol Dongre
Dr. Anuja Deshmukh
Dr. Ashok Shenoy
Dr. Ashwini Budrukhar
Dr. Murad Lala
Dr. Samir Batham
Dr. Sanjay Joshi
Dr. Manoj Mahajan

10.20 am - 10.40 am

TEA/COFFEE BREAK

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Day 2 Hybrid

10.40 am - 11.50 am

Session 2: Key Publication on Laryngeal and Oropharyngeal Cancers

10.40 am - 10.50 am

**Chairpersons : Dr. Vivek Kaushal
Dr. Shekhar Salkar**

Reviewer : Dr. Monali Swain

- Randomized Trial of Radiotherapy Versus Transoral Robotic Surgery for Oropharyngeal Squamous Cell Carcinoma: Long-Term Results of the ORATOR Trial

Author : Anthony C Nichols

Citation : Journal of Clinical Oncology 40, no. 8 (March 10, 2022) 866-875

- Survival and Larynx Preservation in Early Glottic Cancer: A Randomized Trial Comparing Laser Surgery and Radiation Therapy

Author : Pakkanen, Pihla et al.

Citation: International Journal of Radiation Oncology, Biology, Physics, Volume 113, Issue 1, 96 - 100

10.50 am - 11.00 am

Reviewer : Dr. Shwetabh Sinha

- Randomized Trial of Radiation Therapy With Weekly Cisplatin or Cetuximab in Low-Risk HPV-Associated Oropharyngeal Cancer (TROG 12.01) - A Trans-Tasman Radiation Oncology Group Study

Author : Rischin, Danny et al

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 111, Issue 4, 876 - 886

- Result from compare phase III RCT: Dose escalated chemoradiation Vs control in oropharyngeal cancer

Author : Paul Sanghera

Citation: ICHNO-ECHNO 2022: OC-0014

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11.00 am - 11.10 am

Reviewer : Dr. Shivakumar Thiagarajan

- LBA-3: Patient-reported Outcomes in Oropharyngeal Cancer Treated With Definitive Chemoradiation vs. Surgery With Postoperative Radiation With or Without Chemotherapy

Author : M.W. McDonald

Citation : IJROBP 2022: LBA-3: VOLUME 113;ISSUE 1; E2

- Survival analysis of patients with advanced hypopharyngeal cancer comparing patients who received primary surgery to those who received chemoradiation: An analysis of the NCDB

Author : Colleen G. Hochfelde

Citation: Oral Oncol. 2021 Oct;121:105470

11.10 am - 11.15 am

Reviewer : Dr. Nikhil Kalyani

- Dose-escalated intensity-modulated radiotherapy in patients with locally advanced laryngeal and hypopharyngeal cancers: ART DECO, a phase III randomised controlled trial

Author : Nutting, Christopher M. et al

Citation : European Journal of Cancer, Volume 153, 242 - 256

11.15 am - 11.20 am

Reviewer : Dr. Deepak Balasubramanian

- Robotic surgery may improve overall survival for T1 and T2 tumors of the hypopharynx: An NCDB cohort study

Author : Andrey Finegersh

Citation : Oral Oncol. 2021 Oct;121:105440

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11.20 am - 11.50 am

**Chairpersons : Dr. Sandeep De
Dr. Sudeep Sarkar**

- Panel Discussion on Laryngeal & Oropharyngeal Cancer

Moderator : Dr. Vikram Kekatpure

**Panelists : Dr. Rakesh Neve
Dr. Poonam Joshi
Dr. Akshay Kudpaje
Dr. Gunjan Baijal
Dr. Narayan Prasad
Dr. Venkat Radhakrishnan
Dr. Sudhir Nair**

11.50 am - 01.05 pm

Session 3: Key Publication on Nasopharyngeal Cancer

**Chairpersons : Dr. Kaustubh Patel
Dr. Sumit Basu**

11.50 am - 12.05 pm

Reviewer : Dr. Vijay Patil

- Weekly Cisplatin Plus Radiation for Postoperative Head and Neck Cancer (JCOG1008): A Multicenter, Noninferiority, Phase II/III Randomized Controlled Trial
Author : Naomi Kiyota
Citation : Journal of Clinical Oncology 40, no.18;1980-1990
- Results of phase 3 randomized trial for use of docetaxel as a radiosensitizer in patients with head and neck cancer unsuitable for cisplatin-based chemoradiation
Author : Vijay Maruti Patil
Citation : Journal of Clinical Oncology 2022;LBA6003-LBA6003

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12.05 pm - 12.15 pm

- Phase 3 randomized study evaluating the addition of low-dose nivolumab to palliative chemotherapy in head and neck cancer
Author : Vijay Maruti Patil
Citation : Journal of Clinical Oncology 2022; LBA6016

Reviewer : Dr. Swapnil Rane

- A systematic review and recommendations on the use of plasma EBV DNA for nasopharyngeal carcinoma
Author : Lee, Anne W.M. et al.
Citation : European Journal of Cancer, Volume 153, 109 - 122

12.15 pm - 12.25 pm

- Deintensified Chemoradiotherapy for Pretreatment Epstein-Barr Virus DNA-Selected Low-Risk Locoregionally Advanced Nasopharyngeal Carcinoma: A Phase II Randomized Noninferiority Trial
Author : Xiao-Yun Li
Citation : Journal of Clinical Oncology 40, no. 11 (April 10, 2022) 1163-1173

Reviewer : Dr. Gagan Saini

- A Randomized Controlled Trial of Reirradiation Using Diffusion-Weighted MRI Guided Dose-Painting vs. CT-Based Radiotherapy for Locally Recurrent T3 to T4 Nasopharyngeal Carcinoma
Author : Liu, F. et al.
Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 111, Issue 3, S63

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12.25 pm – 12.35 pm

- Five-Year Result After Reduction of the Target Volume of Intensity Modulated Radiotherapy Following Induction Chemotherapy in Locoregionally Advanced Nasopharyngeal Carcinoma: A Phase 3, Multicenter, Randomized Controlled Trial
Author : Xiang, L. et al.
Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 111, Issue 3, S142
Reviewer : Dr. Akhil Kapoor
- Management of suboptimal response to induction chemotherapy in locoregionally advanced nasopharyngeal carcinoma: Re-induction therapy or direct to Radiotherapy?
Author : Ting Liu
Citation : Radiother Oncol. 2021 Oct;163:185-191
- MRI-based radiomics to compare the survival benefit of induction chemotherapy plus concurrent chemoradiotherapy versus concurrent chemoradiotherapy plus adjuvant chemotherapy in locoregionally advanced nasopharyngeal carcinoma: A multicenter study
Author : Hesong Shen
Citation : Radiother Oncol. 2022 Jun;171:107-113

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12.35 pm - 01.05 pm

Chairpersons : Dr. G V Giri

Dr. Pankaj Shah

- Panel Discussion on Nasopharyngeal Cancer

Moderator : Dr. Sarbani Laskar

Panelists : Dr. Deepa Nair

Dr. Devang Bhavsar

Dr. Devendra Chaukar

Dr. Vikas Talreja

Dr. Sayan Paul

Dr. Shekhar Keshri

01.05 pm - 02.05 pm

BREAK

01.30 pm - 02.00 pm

Role of IO and its sequencing strategy in the management of HNSCC (Supported by MSD)

Speaker : Dr. Ashay Karpe

02.05 pm - 03.05 pm

Session 4: Key Publication on Salivary Gland Cancer

02.05 pm - 02.15 pm

Chairpersons : Dr. Yogesh Dabholkar

Dr. Harsh Dhar

- Reviewer : Dr. Richa Vaish**

Evaluation of Surgical Margin Status in Patients With Salivary Gland Cancer

Author : Martin Hanson

Citation : JAMA Otolaryngol Head Neck Surg. 2022;148(2):128-138

- Evaluation of Parotidectomy Defect Reconstruction: A Systematic Review And Metaanalysis

Author : Jacob S Brady

Citation : AHNS 2022: Poster: A135

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02.15 pm - 02.25 pm

Reviewer : Dr. Kinjal Jani

Parotid Gland Stem Cell Sparing Radiation Therapy for Patients With Head and Neck Cancer: A Double-Blind Randomized Controlled Trial

Author : Steenbakkers, Roel J.H.M. et al

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 112, Issue 2, 306 - 316

The impact of head and neck radiotherapy on salivary flow and quality of life: Results of the ORARAD study

Author : Alexander Lin

Citation : Oral Oncol. 2022 Apr; 127:105783

02.25 pm - 02.35 pm

Reviewer : Dr. M. V. Chandrakanth

A phase II trial of all-trans retinoic acid (ATRA) in advanced adenoid cystic carcinoma

Author : Glenn J. Hanna

Citation : Oral Oncol. 2021 Aug;119:105366

Abiraterone Acetate in Patients With Castration-Resistant, Androgen Receptor-Expressing Salivary Gland Cancer: A Phase II Trial

Author : Laura D Locati

Citation : Journal of Clinical Oncology 39, no. 36 (December 20, 2021) 4061-4068

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02.35 pm - 03.05 pm

**Chairpersons : Dr. Punita Lal
Dr. Umang Mittal**

• Panel Discussion on Salivary Gland Cancer

Moderator : Dr. Prathamesh Pai

**Panelists : Dr. Vishal Rao
Dr. Subramanian Iyer
Dr. Rohit Malde
Dr. Tushar Patil
Dr. Pankaj Chaturvedi
Dr. Trinanjan Basu**

03.05 pm - 04.05 pm

Session 5: Key Publication on Thyroid Cancer

**Chairpersons : Dr. K. Pavithran
Dr. Ashok Shenoy**

03.05 pm - 03.15 pm

• **Reviewer : Dr. Sunil Chopade**

Cabozantinib for radioiodine-refractory differentiated thyroid cancer (COSMIC-311): a randomised, double-blind, placebo-controlled, phase 3 trial

Author : Prof. Marcia S Brose

Citation : VOLUME 22, ISSUE 8, P1126-1138, AUGUST 01, 2021

• Dabrafenib plus trametinib in patients with BRAF V600E-mutant anaplastic thyroid cancer: updated analysis from the phase II ROAR basket study

Author : V. Subbiah

Citation : Ann Oncol. 2022 Apr;33(4):406-415

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03.15 pm - 03.25 pm

Reviewer : Dr. Apurva Garg

- Thyroidectomy without Radioiodine in Patients with Low-Risk Thyroid Cancer

Author : Sophie Leboulleux

Citation : N Engl J Med. 2022 Mar 10;386(10):923-932

- Prophylactic Central Neck Dissection for cN1b Papillary Thyroid Carcinoma: A Systematic Review and Meta-Analysis

Author : Xing-Qiang Yan

Citation : Front Oncol. 2022 Jan 14;11:803986

03.25 pm - 03.35 pm

Reviewer : Dr. Vikas Talreja

- Association of Multifocality With Prognosis of Papillary Thyroid Carcinoma A Systematic Review and Meta-analysis

Author : Hyeonkyeong Kim

Citation : JAMA Otolaryngol Head Neck Surg. 2021 Oct 1;147(10):847-854

- Clinical and Anatomical Factors Affecting Recurrent Laryngeal Nerve Paralysis During Thyroidectomy via Intraoperative Nerve Monitorization

Author : Nurcihan Aygun

Citation : Front Surg. 2022 Apr 28;9:867948

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03.35 pm - 04.05 pm

**Chairpersons : Dr. Mehul Bhansali
Dr. Shaleen Kumar**

- Panel Discussion on Thyroid Cancer

Moderator : Dr. Atul Sharma

Panelists : Dr. Madhuri Shimpi

Dr. Kanhu Patro

Dr. Krishna Kumar T

Dr. Pawan Rane

Dr. Vinayak Maka

Dr. Bharath Rangarajan

Dr. Sagar Vaishampayan

04.05 pm - 04.15 pm

TEA/COFFEE BREAK

04.15 pm - 05.15 pm

Session 6: Key Publication on
Recurrent/metastatic Head And Neck Cancer

04.15 pm - 04.25 pm

Chairperson : Dr. Lalit Mohan Sharma

Reviewer : Dr. Rushabh Kothari

- Nivolumab (N) + ipilimumab (I) vs EXTREME as first-line (1L) treatment (tx) for recurrent/metastatic squamous cell carcinoma of the head and neck (R/M SCCHN): Final results of CheckMate 651

Author : Athanassios Argiris

Citation : Annals of Oncology (2021) 32 (suppl_5): S1283-S1346

- Is there a role of local treatment for oligometastatic scchn in the immunotherapy era

Author : Victoria Espeli

Citation : ICHNO-ECHNO 2022:PO-0086

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04.25 pm - 04.35 pm

Reviewer : Dr. Priya Tiwari

- Cetuximab, docetaxel, and cisplatin versus platinum, fluorouracil, and cetuximab as first-line treatment in patients with recurrent or metastatic head and neck squamous-cell carcinoma (GORTEC 2014-01 TPExtreme): a multicentre, open-label, randomised, phase 2 trial

Author : Joël Guigay

Citation : Lancet Oncol 2021; 22: 463-75

- A phase II trial of pembrolizumab and cabozantinib in patients (pts) with recurrent metastatic head and neck squamous cell carcinoma (RMHNSCC)

Author : Nabil F. Saba

Citation : Journal of Clinical Oncology 2022 40:16_suppl, 6008-6008

04.35 pm - 04.45 pm

Reviewer : Dr. Nandini Menon

- Nivolumab in Recurrent/Metastatic Squamous Cell Carcinoma of Head and Neck: A Tertiary Cancer Center Experience

Author : Ananya Pareek

Citation : South Asian J Cancer 2021;00:1-4

- Salvage surgery for recurrent squamous cell carcinoma of the head and neck: Systematic review and meta-analysis

Author : Bulbul MG

Citation : Head Neck. 2022 Jan;44(1):275-285

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04.45 pm - 05.15 pm

**Chairpersons : Dr. Bharat Parikh
Dr. Shekhar Patil**

- Panel Discussion On Recurrent/metastatic Head And Neck Cancer

Moderator : Dr. Ranga Rao

Panelists : Dr. B. Sainath

Dr. Suman Mallik

Dr. Ankhur Bhal

Dr. Ashay Karpe

Dr. Ghanshyam Biswas

Dr. Sadashivudu Gundeti

Dr. Alok Goel

05.15 pm - 06.15 pm

Session 7: Key Publication On Special Population (RARE/HPV/ELDERLY)

**Chairpersons : Dr. S. V. S. S. Prasad
Dr. G. K. Jadhav**

05.15 pm - 05.25 pm

- Reviewer : Dr. Karan Gupta**

A Randomized Trial of Radiotherapy vs. Trans-Oral Surgery for Treatment De-Escalation in HPV-Associated Oropharyngeal Squamous Cell Carcinoma (ORATOR2)

Author : Palma

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 111, Issue 5, 1324 - 1325

- Surgery For The Treatment of HPV-negative Squamous Cell Carcinoma of The Oropharynx - A Systematic Review And Meta-analysis

Author : Erica H McArdle

Citation : AHNS 2022: Poster: A104

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05.25 pm - 05.35 pm

Reviewer : Dr. Deepanjali Adulkar

- Hypofractionated Vs standard radiotherapy in elderly unfit patients with HN cancer- ELAN-RT trial

Author : Cecile ortholan

Citation : ICHNO-ECHNO 2022: OC-0012

- Long-Term Results for MC1273, A Phase II Evaluation of De-Escalated Adjuvant Radiation Therapy for Human Papillomavirus Associated Oropharyngeal Squamous Cell Carcinoma (HPV+ OPSCC)

Author : Ma, D.J. et al.

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 111, Issue 3, S61

05.35 pm - 05.45 pm

Reviewer : Dr. Babita Kataria

- Efficacy and safety of immune checkpoint inhibitors in elderly patients (≥ 70 years) with squamous cell carcinoma of the head and neck

Author : Saleh, Khalil et al.

Citation : European Journal of Cancer, Volume 157, 190 - 197

- Detectable Postoperative Circulating Tumor Human Papillomavirus DNA and Association with Recurrence in Patients With HPV-Associated Oropharyngeal Squamous Cell Carcinoma

Author : Routman, David M. et al.

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 113, Issue 3, 530 - 538

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05.45 pm - 06.15 pm

**Chairpersons : Dr. Arnab Gupta
Dr. Deepak Sarin**

• Panel Discussion On Special Population
(RARE/HPV/ELDERLY)

Moderator : Dr. Nikhilesh Borkar

**Panelists : Dr. Rakesh Katna
Dr. Venkata Pradeep Babu
Dr. Shailesh Bondarde
Dr. Chakor Vora
Dr. Gautam Sharan**

Sponsored Session

06.15 pm - 06.35 pm

• Optimizing treatment for R/M SCCHN with
immune checkpoint inhibitors
(Supported by BMS)
Speaker : Dr. Vijay Patil

06.35 pm - 06.50 pm

• Individualizing patient journey in RM SCCHN
(Supported by Merck)
Speaker : Dr. Suhas Agre

06.50 pm - 07.05 pm

• Approach to Salivary Gland tumor and Role
of anti-HER2 therapy (Supported by Zydus)
Speaker : Dr. Vijay Patil
(Supported by DRL)
Chairperson : Dr. Nagraj Huilgol

07.05 pm - 07.15 pm

• Radiation Dermatitis the unwelcome
consequence of a life saving therapy
Speaker : Dr. Anuj Kumar S

07.15 pm - 07.30 pm

• Strata XRT: A novel full contact silicone-based
gel dressing in prevention and treatment of
Radiation Dermatitis
Speaker : Dr. Ajau Rao

07.30 pm - 07.35 pm

• Q & A

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- | | |
|---------------------|--|
| 07.35 pm - 07.50 pm | • Advances in Novel Formulations of Taxanes in Head & Neck Cancer (Supported by Intas)
Speaker : Dr. Vijay Patil |
| 07.50 pm - 08.05 pm | • Personalised Therapy in Treatment of BRAF V600E mutated Anaplastic Thyroid Cancer (Supported by Novartis)
Speaker : Dr. Vijay Patil |

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7th August 2022

Day 3 Hybrid

09.30 am - 10.05 am

Session 8: Key Publication in Supportive Care

09.30 am - 09.40 am

**Chairpersons : Dr. Anuradha Daptardar
Dr. Sharad Desai**

Reviewer : Dr. Mansi Khanderia

- Randomized Phase 3, Double-Blind, Placebo-Controlled Study of Prophylactic Gabapentin for the Reduction of Oral Mucositis Pain During the Treatment of Oropharyngeal Squamous Cell Carcinoma

Author : Cook, Andrew et al.

Citation : International Journal of Radiation Oncology, Biology, Physics, Volume 112, Issue 4, 926 – 937

- Use of Prophylactic Steroids to Prevent Hypocalcemia and Voice Dysfunction in Patients Undergoing Thyroidectomy A Randomized Clinical Trial

Author : Adeel Abbas Dhahri

Citation : JAMA Otolaryngol Head Neck Surg. 2021;147(10):866-870

09.40 am - 09.50 am

Reviewer : Dr. Y. T. Shivshankar

- Use of deep learning to predict the need for aggressive nutritional supplementation during head and neck radiotherapy

Author : Michael Dohopolski

Citation : Radiother Oncol. 2022 Jun;171:129-138

- Nutritional Support During Radiotherapy for Head and Neck Cancer: The Role of Prophylactic Feeding Tube Placement

Author : Jormain Cady

Citation : Clin J Oncol Nurs. 2007 Dec;11(6):875-80

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5th Annual Review on Head & Neck Cancers

5th, 6th & 7th August, 2022

7th August 2022

Day 3 Hybrid

09.50 am - 09.55 am

Reviewer : Dr. Arun Balaji

Long-term swallowing-related outcomes in oral cancer patients receiving proactive swallowing therapy

Author : Wen-Hsuan Tseng

Citation : Oral Oncol. 2021 Nov;122:105569

09.55 am - 10.05 am

Q & A

10.05 am - 11.05 am

Session 9: Key Publication on Locally Advanced-HN&SCC

10.05 am - 10.15 am

**Chairpersons : Dr. Govind Babu
Dr. A K Anand**

Reviewer : Dr. Bhuvan Chugh

Avelumab-cetuximab-radiotherapy versus standards of care in patients with locally advanced squamous cell carcinoma of head and neck (LA-SCCHN): Randomized phase III GORTEC-REACH trial

Author : Jean Bourhis

Citation : Annals of Oncology (2021)

32 (suppl_5): S1283-S1346

Paclitaxel Based CCRT Is an Acceptable Alternative for Cisplatin Based CCRT in the Treatment of Locally Advanced (Stage IVA) Head Neck Carcinoma

Author : Md. Zillur Rahman Bhuiyan

Citation : Cancer Research Journal.2021; 9(3): 166-170

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5th Annual Review on Head & Neck Cancers

5th, 6th & 7th August, 2022

7th August 2022

Day 3 Hybrid

10.15 am - 10.25 am

Reviewer : Dr. Kumardeep Dutta

• The role of induction chemotherapy in patients with locally advanced head and neck squamous cell carcinoma: A nationwide population-based matched study

Author : Meng-Che Hsieh

Citation : Oral Oncol. 2022 May;128:105848

• Quality of life in patients with locally advanced head and neck cancer treated with concurrent chemoradiation with cisplatin and nimotuzumab versus cisplatin alone – Additional data from a phase 3 trial

Author : Nandini Menon

Citation : Oral Oncol. 2021 Nov;122:105517

10.25 am - 10.35 am

Reviewer : Dr. Rakesh Pinninti

• Six-year follow-up from the weekly-three-weekly study comparing cisplatin once-a-week to once-every-three-weeks as concurrent chemoradiation for locally advanced head and neck squamous cell carcinoma

Author : Vanita Noronha

Citation : Journal of Clinical Oncology 2022 40:16_suppl, 6071-6071

• A randomized phase II study evaluating concurrent or sequential fixed-dose immune therapy in combination with cisplatin and intensity-modulated radiotherapy in intermediate- or high-risk, previously untreated, locally advanced head and neck cancer (LA SCCHN)

Author : David Anthony Clump

Citation : Journal of Clinical Oncology 2022 40:16_suppl, 6007-6007

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5th Annual Review on Head & Neck Cancers

5th, 6th & 7th August, 2022

7th August 2022

Day 3 Hybrid

10.35 am - 11.05 am
10.35 am - 11.05 am

Chairperson : Dr. Manisha Singh
Panel Discussion on Locally Advanced-HN&SCC
Moderator : Dr. Nandini Menon
Panelists : Dr. Simon Pavamani
Dr. Munish Gairola
Dr. Sachin Hingmire
Dr. Ram Abhinav
Dr. Tanmoy Mandal
Dr. Vijay Sharnangat

11.05 am - 11.20 am

TEA/COFFEE BREAK

11.20 am - 11.50 am

Session 10: Key Publication on Biomarkers in H&N Cancer

11.20 am - 11.50 am

Chairperson : Dr. Anurag Mehta
Reviewer : Dr. Neha Mittal
Key Publication on Biomarkers in H&N Cancer

11.50 am - 12.15 pm

Session 11: HEAD AND NECK CANCERS : Interventions and Others

11.50 am - 12.00 pm

Chairpersons : Dr. Vijay Haribhakti
Dr. Nagraj Huilgol
Reviewer : Dr. Rahul Kulkarni
Aspiration pneumonia in head and neck cancer patients undergoing concurrent chemoradiation from India: Findings from a post hoc analysis of a phase 3 study
Author : Patil V
Citation : Cancer Medicine 2021;10:6725-35

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5th Annual Review on Head & Neck Cancers

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7th August 2022

Day 3 Hybrid

12.00 pm - 12.10 pm

• Post hoc analysis of the screening log of phase III investigator-initiated randomized clinical trial comparing palliative oral metronomic versus intravenous chemotherapy in head-and-neck cancer

Author : Sachin Dhumal

Citation : Cancer Res Stat Treat 2021;4:642-6

Reviewer : Dr. Rakesh Roy

• Neoadjuvant PD-1/PD-L1 Inhibitors for Resectable Head and Neck Cancer: A Systematic Review and Meta-analysis

Author : Razan Masarwy

Citation : JAMA Otolaryngol Head Neck Surg. 2021 Oct 1;147(10):871-878

• Prognostic factor analysis and long-term results of the TAX 323 (EORTC 24971) study in unresectable head and neck cancer patients

Author : Petr Szturz

Citation : Eur J Cancer. 2021 Oct;156:109-118

12.10 pm - 12.15 pm

Reviewer : Dr. Anshul Singla

• A Multi-Institutional Analysis of Late Complications In Scapula, Fibula, and Osteocutaneous Radial Forearm Free Flap

Author : Craig A Bollig

Citation : AHNS 2022: Oral Paper: AHNS33

12.15 pm Onwards

Industrial Symposium and Vote of Thanks Followed by Lunch

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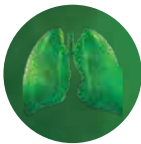
KEYTRUDA for the treatment of patients with **unresectable or metastatic melanoma**.



KEYTRUDA + CHEMOTHERAPY* for the first-line treatment of patients with **metastatic non-squamous Non-small Cell Lung Cancer (NSCLC)**, with no EGFR or ALK genomic tumor aberrations.



KEYTRUDA + CHEMOTHERAPY^ for first-line therapy of **metastatic or with unresectable, recurrent Head and Neck Squamous Cell Carcinoma (HNSCC)**.



KEYTRUDA + CHEMOTHERAPY\$ for the first-line treatment of patients with **metastatic squamous NSCLC**.



KEYTRUDA MONOTHERAPY for first-line therapy of **metastatic or with unresectable, recurrent HNSCC** whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1].



KEYTRUDA MONOTHERAPY for the second-line treatment of patients with **locally advanced or metastatic urothelial carcinoma** who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with **platinum-containing chemotherapy**.

Reference: Keytruda India PI • *Pemetrexed and platinum containing chemotherapy (cisplatin/carboplatin). \$Carboplatin and either paclitaxel or paclitaxel protein-bound ^Platinum and 5-fluorouracil (5-FU)

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Mode of reporting the adverse event	Details
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E-mail	dpoc_india@merck.com
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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.

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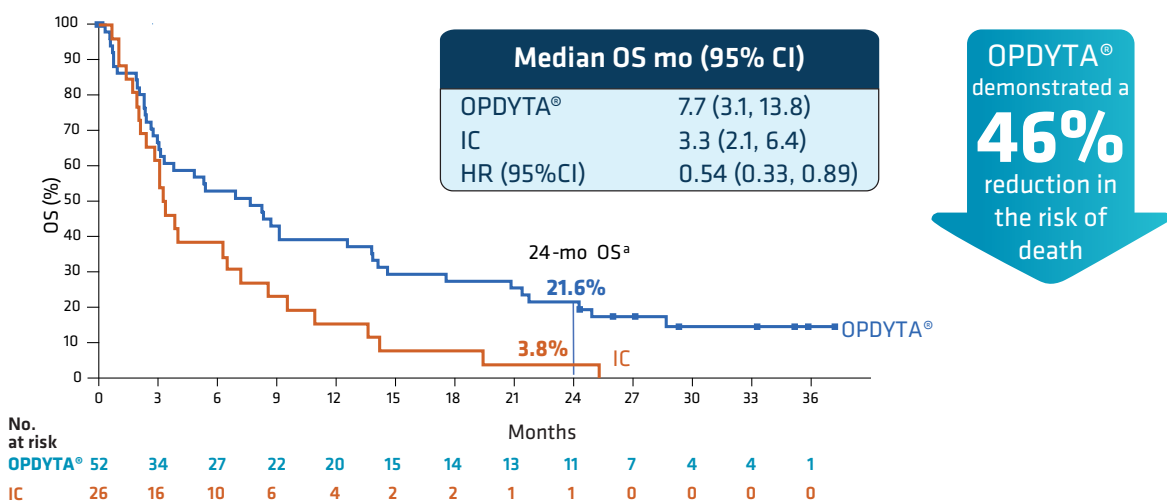
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CheckMate 141 was a randomized, open-label, phase 3 trial in patients with R/M SCCHN who had progressed on or within 6 months after platinum-based therapy

5X survival benefit with early usage of OPDYTA®



* Based on Kaplan-Meier estimates and minimum follow-up of 24.25 months. Sept 2017 database lock. Data on File. OPDYTA 455. Bristol-Myers Squibb Company, Princeton, NJ. 1L, first line; ASCO, American Society of Clinical Oncology; CI, confidence interval; HR, hazard ratio; IC, Investigators Choice; mo, months; OPDYTA, Nivolumab; OS, overall survival; R/M, recurrent/metastatic; SCCHN, squamous cell carcinoma of the head and neck.

Outcomes were analyzed post hoc in patients who were platinum- refractory in the primary/adjuvant setting and received OPDYTA® or IC (cetuximab, docetaxel and methotrexate) as 1L therapy for R/M SCCHN in Checkmate 141

At 12 months treatment related Grade 3- 4 AEs were 27.5 % vs 32% for OPDYTA and IC respectively

Reference – 1. Ferris RL, et al. J Oral Oncol 2018 Jun; 81: 45 – 51

There were 2 deaths in Opdyta arm and 1 death in IC arm

1L, first line; ASCO, American Society of Clinical Oncology; CI, confidence interval; HR, hazard ratio; IC, Investigators Choice; mo, months; OPDYTA, Nivolumab; OS, overall survival; R/M, recurrent/metastatic; SCCHN, 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. a. Based on Kaplan-Meier estimates and minimum follow-up of 24.25 months. Sept 2017 database lock. Data on File. OPDYTA 455. Bristol-Myers Squibb Company.

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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; 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, 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 with 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. **Nivolumab in combination with ipilimumab (NSCLC):** The recommended dose of nivolumab is 3 mg/kg administered intravenously over a period of 30 minutes every 2 weeks combined with ipilimumab 1 mg/kg administered intravenously over a period of 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. For all combination therapy.

When administered in combination with ipilimumab, with ipilimumab and chemotherapy, or with other therapeutic agents, nivolumab should be given first followed by ipilimumab (if applicable) and then chemotherapy or other therapeutic agents 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 diarrhoea or colitis. Withhold Nivolumab monotherapy for Grade 3 diarrhoea or colitis. Permanently discontinue nivolumab + ipilimumab for Grade 3 & 4 diarrhoea or colitis. Permanently discontinue nivolumab monotherapy for Grade 4 diarrhoea 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 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 hypophosphitis. 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 4 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 13 dated 22 Jun 2022

Issued – 28 Jul 2022 Before prescribing, consult full prescribing information.

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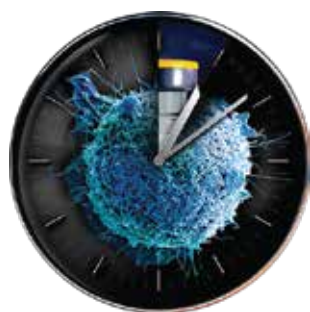
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In 1L RM SCCHN:

- Erbitux+CT provides consistently high mOS and ORR³⁻⁷
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1. Bonner JA et al. N Engl J Med 2006; 354: 567-568, 2. Curran et al. J Clin Oncol 25: 2191-2197, 3. Guigay J, et al. Ann Oncol 2015;26:1941-1947; 4. Bossi P, et al. Ann Oncol 2017;28:2820-2826; 5. Tahara M, et al. Ann Oncol 2018;29:1004-1009; 6. Friesland S, et al. ASCO 2018 (Abstract 6032); 7. Vermorken JB, et al. N Engl J Med 2008;359:1116-1127; 8. Mesia R et al. Ann Oncol 2010;; 21:1967-1973

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Warning: To be sold by retail on the prescription of a Oncologist only
Before prescribing ERBITUX, please consult full prescribing information. **Presentation:** *ERBITUX 5 mg/mL solution for infusion. Excipients: sodium chloride, glycine, polysorbate 80, citric acid monohydrate, sodium hydroxide, water for injections. **Indications:** Epidermal growth factor receptor-expressing, RAS wild-type metastatic colorectal cancer (mCRC): in combination with irinotecan-based chemotherapy (CT), or in first-line in combination with FOLFOX, or as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. Squamous cell carcinoma of the head and neck (SCCHN): in combination with radiation therapy (RT) for locally advanced (LA) disease or with platinum-based chemotherapy (pt-CT) for recurrent and/or metastatic (R/M) disease. **Dosage and administration:** Once a week, intravenously with an infusion pump, gravity drip or a syringe pump; separate infusion line. Initial dose 400 mg/m² (should be given slowly with max. infusion rate: 5 mg/min; the recommended infusion period is over 120 mins); subsequent weekly doses 250 mg/m² (Max. infusion rate: 10 mg/min; recommended over 60 mins). Supervision/monitoring by a physician experienced in antineoplastic therapy throughout infusion and for at least one hour afterwards is required. Resuscitation equipment must be ensured. Prior to first infusion: premedication with antihistamines and corticosteroids at least 1 hour prior to administration of ERBITUX; also recommended for all subsequent infusions. Administer CT not earlier than one hour after ERBITUX infusion. **mCRC:** administer ERBITUX until disease progression. Wild-type RAS tumor status must be verified prior to first infusion by an experienced laboratory using validated test methods. **LA SCCHN:** start ERBITUX therapy one week before RT and continue throughout treatment. **R/M SCCHN:** administer ERBITUX in combination with pt-CT and continue until disease progression. **Special Populations:** *Elderly:* no dose adjustment required (limited experience in patients ≥75 years). *Pediatric patients* (<18 years): efficacy not established, no new safety signals. *Others:* only patients with adequate renal, hepatic and hematological parameters have been investigated. **Contraindications:** Known severe hypersensitivity reactions (grade 3/4 NCI CTCAE). In combination with oxaliplatin-containing CT if mutated/unknown RAS status. Contraindications for concomitantly used CT or RT must be considered. **Special warnings and precautions:** *Severe infusion-related reactions (IRRs) including anaphylactic reactions:* May commonly occur, in some cases with fatal outcome; immediate and permanent discontinuation of ERBITUX therapy; may necessitate emergency treatment. May be anaphylactic or anaphylactoid in nature or represent a cytokine release syndrome. Symptoms may occur during the first infusion and for up to several hours afterwards or with subsequent infusions and may include bronchospasm, urticaria, increase or decrease in blood pressure, loss of consciousness or shock. In rare cases, angina pectoris, myocardial infarction or cardiac arrest have been observed. The risk for anaphylactic reactions is much increased in patients with a history of allergy to red meat or tick bites or positive results of tests for IgE antibodies against Erbitux. *Mild/moderate IRRs:* decrease infusion rate, also for all subsequent infusions. Closely monitor patients with reduced performance status (PS) and pre-existing cardio-pulmonary disease. *Skin reactions:* oral tetracyclines and topical 1% hydrocortisone cream with moisturizer may be considered for prophylactic use and medium to high-potency topical corticosteroids or oral tetracyclines for treatment (acc. to clinical practice guidelines). *Severe skin reaction* (≥grade 3): interrupt treatment, only resume if reaction resolves to grade 2. Second or third occurrence of severe skin reactions: resume at lower dose (200 mg/m² after second, 150 mg/m² after third) only if reaction resolves to grade 2. Fourth occurrence or failure to resolve to grade 2 during interruption: permanent discontinuation. *Interstitial lung disease:* if diagnosed, discontinuation and appropriate treatment. *Electrolyte disturbances:* determination of serum electrolyte levels recommended prior to and periodically during treatment. Electrolyte repletion (e.g. hypomagnesaemia; hypokalaemia as a consequence of diarrhea; hypocalcemia, particularly in combination with pt-CT) is recommended. *Neutropenia and related infectious complications:* careful monitoring is recommended particularly in patients experiencing skin lesions, mucositis or diarrhea that may facilitate the occurrence of infections. *Severe and sometimes fatal cardiovascular events:* increased frequency associated with age ≥ 65 years or PS has been observed. Patient cardiovascular status, PS and concomitant administration of cardiotoxic compounds (e.g. fluoropyrimidines) should be taken into account. *Acute or worsening symptoms of keratitis:* refer promptly to an ophthalmologist, consider benefit/risk of continuing use. *Confirmed ulcerative keratitis:* interruption or discontinuation of ERBITUX. Use with caution in patients with history of keratitis, ulcerative keratitis or severe dry eye (e.g. use of contact lenses). *CR patients with mutated/unknown RAS status:* ERBITUX should not be used since negative effects on PFS and OS as add-on to FOLFOX4 have been reported in RAS mutated tumors. There is limited experience in combination with RT in mCRC. **Fertility, pregnancy and lactation:** Only use during pregnancy or in women with inadequate contraception if potential benefits justify potential risks to fetus. Breast-feeding during treatment and 2 months later is not recommended. Effects on male/female fertility have not been evaluated. **Undesirable effects:** *Very common* (≥1/10): skin reactions (e.g. acne-like rash and/or pruritus, dry skin, desquamation, hypertrichosis, or nail disorders, single cases of skin necrosis), hypomagnesaemia, mild/moderate IRRs (e.g. fever, chills, dizziness, dyspnea), increased liver enzyme levels and mucositis, in some cases severe. Mucositis may lead to epistaxis. *Common* (≥1/100, <1/10): headache, conjunctivitis, diarrhea, nausea, vomiting, fatigue, dehydration, hypocalcemia, anorexia, weight loss, severe IRRs. *Uncommon* (≥1/1000, <1/100): blepharitis, keratitis, deep vein thrombosis, pulmonary embolism or interstitial lung disease. *Very rare* (<1/10,000): Stevens-Johnson syndrome/toxic epidermal necrolysis. *Frequency not known:* superinfection of skin lesions with subsequent complications (e.g. cellulitis, erysipelas, staphylococcal scalded skin syndrome, necrotising fasciitis, sepsis), aseptic meningitis. In combination with local RT in SCCHN: typical undesirable effects of RT (e.g. mucositis, radiation dermatitis, dysphagia or leukopenia, mainly as lymphocytopenia). In combination with ERBITUX: slightly higher rates of severe acute radiation dermatitis, mucositis and late RT-related events. **Interactions:** *Fluoropyrimidines:* increased frequency of hand-foot syndrome and cardiac ischaemia (e.g. myocardial infarction and congestive heart failure). *Capecitabine and oxaliplatin (XELOX):* frequency of severe diarrhoea may be increased. *pt-CT:* increased frequency of severe leukopenia/neutropenia, which may lead to a higher rate of febrile neutropenia, pneumonia and sepsis. Storage: Store in a refrigerator (2°C – 8°C) Shelf life: 48 months

Date of Information: June 2019 Based on CCDS of Cetuximab V.16.0 dated 28th June 2018.
For further information refer to full prescribing information or write to:

Merck Specialities Pvt Ltd.,
Godrej One, 8th Floor, Pirojsha Nagar, Eastern Express Highway, Vikhroli (East) Mumbai – 400079
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