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6th Annual Review on Head & Neck Cancers

26th – 27th August, 2023

2022 **VIRTUAL** MEETING 2023

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Dr. V Kannan

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Dr. Nandini Menon
Dr. Suparna Rao
Dr. Rakesh Katna
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Welcome Address

On behalf of the organizing committee and Mumbai Oncology Association, we are pleased to invite you to the "6th Annual Review on Head and Neck Cancers Conference". The conference will take place Virtually on the 26th and 27th of August 2023.

The 6th Annual Review on Head and Neck Cancers Conference 2023 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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08:00 am - 9:00 am	REGISTRATION
09:00 am - 10:20 am	**SESSION 1: KEY PUBLICATION ON ORAL CANCER**
09:00 am - 09:10 am	**CHAIRPERSONS: Dr. Murad Lala** **Reviewer: Dr. Shilpi Sharma** Stratification of surgical margin distances by the millimeter on local recurrence in oral cavity cancer: A systematic review and meta-analysis. **Author:** Kurtis Young BS **Citation:** Head Neck. 2023 May;45(5):1305-1314.
	Marginal versus Segmental Mandibulectomy in the Treatment of Oral Cavity Cancer: A Systematic Review and Meta-analysis. **Author:** Carlos Miguel Chiesa-Estomba **Citation:** Int Arch Otorhinolaryngol. 2023 April
09:10 am - 09:25 am	**Reviewer: Dr. Dodul Mondal** Brachytherapy and osteoradionecrosis in patients with base of tongue cancer. **Author:** Daniel Danielsson **Citation:** Acta Otolaryngol. 2023 Jan;143(1):77-84.
	A Phase II Study of Volume and Dose De-Intensification Following Transoral Robotic Surgery (TORS) and Neck Dissection for p16+ Oropharyngeal Squamous Cell Carcinoma. **Author:** J.N. Lukens **Citation:** International Journal of Radiation Oncology, Biology, Physics. Oral scientific session.138, 114(3), S24-S25, NOVEMBER 01, 2022

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	Oral cavity adjuvant therapy (OCAT) -a phase III, randomized controlled trial of surgery followed by conventional RT (5 fr/wk) versus concurrent CT-RT versus accelerated RT (6fr/wk) in locally advanced, resectable, squamous cell carcinoma of oral cavity. **Author:** Sarbani G. Laskar **Citation:** Eur J Cancer. 2023 Mar;181:179-187.
09:25 am - 09:35 am	**Reviewer: Dr. Sunil Chopade** Association of Neoadjuvant Pembrolizumab for Oral Cavity Squamous Cell Carcinoma With Adverse Events After Surgery in Treatment-Naive Patients. **Author:** Alice L Tang **Citation:** JAMA Otolaryngol Head Neck Surg. 2022 Oct 1;148(10):935-939
	The optimal number of examined lymph nodes for accurate nodal staging and favorable prognosis of oral tongue squamous cell carcinoma. **Author:** Lingdun Zhuge **Citation:** Oral Oncol. 2023 May;140:106368.
09:35 am - 09:50 am	**Reviewer: Dr. Rakesh Neve** Definitive Surgery after Neoadjuvant Chemotherapy for Locally Advanced Oral Cavity Cancers: Experience from a Tertiary Care Center. **Author:** Mansi Agrawal **Citation:** South Asian J Cancer 2023;00(00):00–00

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	Use of Intraoperative Frozen Section to Assess Final Tumor Margin Status in Patients Undergoing Surgery for Oral Cavity Squamous Cell Carcinoma. **Author:** Sallie M Long **Citation:** JAMA Otolaryngol Head Neck Surg. 2022 Oct 1;148(10):911-917.
	Optimized decision support for selection of transoral robotic surgery or (chemo)radiation therapy based on posttreatment swallowing toxicity. **Author:** Mehdi Hemmati **Citation:** Cancer Med. 2023 Feb;12(4):5088-5098.
09:50 am - 10:20 am	**PANEL DISCUSSION ON LOCALLY ADVANCED ORAL CAVITY CANCER**
	CHAIRPERSONS: Dr. Deepak Parikh **MODERATOR: Dr. Arvind Krishnamurthy** **PANELISTS: Dr. Ashwini Budrukkar, Dr. Mandar Deshpande, Dr. Krishnakumar T, Dr. Shilpi Sharma, Dr. Dodul Mondal, Dr. Sunil Chopade, Dr. Rakesh Neve, Dr. Riddhi Trivedi**
10:20 am -10:40 am	**TEA/COFFEE BREAK**
10:40 am - 12:05 pm	**SESSION 2: Key Publications on Oropharyngeal cancer**
	CHAIRPERSON: Dr. Sandeep De, Dr. Sudeep Sarkar, Dr. Yogesh Dabolkar
10:40 am - 10:45 am	**Reviewer: Dr. Nandini Menon** . Prognostic implications of p16 and HPV discordance in oropharyngeal cancer (HNCIG-EPIC-OPC): a multicentre, multinational, individual patient data analysis. **Author:** Prof Hisham Mehanna, FRCS **Citation:** Lancet Oncol. 2023 Mar;24(3):239-251.

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10:45 am - 10:55 am	**Reviewer: Dr. Monali Swain** Similar long-term swallowing outcomes for accelerated, mildly-hypofractionated radiotherapy compared to conventional fractionation in oropharyngeal cancer: A multi-centre study. **Author:** James M Price **Citation:** Radiother Oncol. 2022 Jul;172:111-117
	Patient Reported Outcomes (PROs) in MC1675, De-Escalated Adjuvant Radiation Therapy (DART) vs. Standard of Care Adjuvant Radiation Therapy (SOC) for HPV Associated Oropharyngeal Squamous Cell Carcinoma. **Author:** D.M. Routman **Citation:**International Journal of Radiation Oncology,Biology, Physics. Oral scientific session. S25. Abstract 139.
10:55 am - 11:05 am	**Reviewer: Dr. Shwetabh Sinha** Long-Term Toxic Effects, Swallow Function, and Quality of Life on MC1273: A Phase 2 Study of Dose De-escalation for Adjuvant Chemoradiation in Human Papillomavirus-Positive Oropharyngeal Cancer. **Author:** Katharine Price **Citation:** Int J Radiat Oncol Biol Phys. 2022 Oct 1;114(2):256-265.

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	Toxicity Profiles and Survival Outcomes Among Patients With Nonmetastatic Oropharyngeal Carcinoma Treated With Intensity-Modulated Proton Therapy vs Intensity-Modulated Radiation Therapy. **Author:** Irini Youssef **Citation:** JAMA Netw Open. 2022 Nov 1;5(11):e2241538.
11:05 am - 11:15 am	**Reviewer: Dr. Shivakumar Thiagarajan** The Impact of Surgical Resectability on Outcomes for Patients Undergoing Primary Radiation Treatment for Human Papillomavirus-Related Oropharyngeal Cancer. **Author:** Naif Fnais, MD **Citation:** Int J Radiat Oncol Biol Phys. 2022 Jul 1;113(3):521-529.
	Outcomes by time to adjuvant therapy in E3311, a phase II trial of transoral surgery (TOS) followed by pathology-based adjuvant treatment in HPV-associated (HPV+) oropharynx cancer (OPC): A trial of the ECOG-ACRIN Cancer Research Group. **Author:** Robert L. Ferris MD, PhD **Citation:** ASCO Annual Meeting 2023: Abstract 6036
11:15 am - 11:25 am	**Reviewer: Dr. Nikhil Kalyani** Reduced Aspiration Rates for 50 Gy Postoperative Radiation in HPV-Associated Oropharynx Cancer in E3311: A Trial of the ECOG-ACRIN Cancer Research Group. **Author:** K.A. Hutcheson **Citation:** International Journal of Radiation Oncology, Biology, Physics. Oral scientific session: S27. Abstracts 142.

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	Treatment of oropharyngeal squamous cell carcinoma: Is swallowing quality better after TORS or RT? **Author:** Flaminia Campo **Citation:** Radiother Oncol. 2023 Feb 20;183:109547.
11:25 am - 11:35 am	**Reviewer: Dr. Pranav Chadha**
	Clinical outcomes of ipsilateral versus bilateral neck irradiation for unilateral tonsillar cancer. **Author:** E. Yang **Citation:** ESTRO 2023:PO-1174
	A Prospective study of mucosal sparing radiation therapy in resected oropharyngeal cancer patients. **Author:** Justin D Anderson **Citation:** Int J Radiat Oncol Biol Phys. 2023 Jan 1;115(1):192-201.
11:35 am - 12:05 pm	**PANEL DISCUSSION ON HPV -VE OROPHARYNGEAL CANCER**
	CHAIRPERSONS: Dr. Shishir Shetty, Dr. Sharmila Agarwal **MODERATOR: Dr. Atul Sharma** **PANELISTS: Dr. Rohit Malde, Dr. Poonam Joshi, Dr. Sudhir Nair, Dr. Trinanjan Basu, Dr. Nandini Menon, Dr. Monali Swain, Dr. Shwetabh Sinha, Dr. Shivakumar Thiagarajan, Dr. Nikhil Kalyani, Dr. Pranav Chadha**

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12:05 pm – 01:10 pm	**SESSION 3: Key Publications on Laryngeal & Hypopharyngeal cancer**
12:05 pm – 12:20 pm	**CHAIRPERSON: Dr. Sarbani Ghosh Laskar** **Reviewer: Dr. Samir Batham** Hypofractionated (2.75 Gy per fraction) versus Conventionally Fractionated Primary Radiotherapy for T2N0M0 Carcinoma of the Glottis. **Author:** Josef Kovarik **Citation:** Int Arch Otorhinolaryngol 2023;27(1):e16–e23.
	Association of Primary Tumor Volume With Survival in Patients With T3 Glottic Cancer Treated With Radiotherapy: A Study of the Canadian Head & Neck Collaborative Research Initiative. **Author:** Nauman H Malik **Citation:**JAMA Otolaryngol Head Neck Surg. 2023 Feb 1;149(2):103-109.
	Predictors for laryngo-esophageal function preservation after radiotherapy for hypopharyngeal cancer. **Author:** A. Nakajima **Citation:** ESTRO 2023:PO-1186
12:20 pm – 12:30 pm	**Reviewer: Dr. Vidisha T** Pharyngocutaneous Fistula Following Primary Total Laryngectomy: a Meta-analysis. **Author:** Karthik Nagaraja Rao **Citation:** Indian J Surg Oncol. 2022 Dec;13(4):797-808.

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	Survival and Quality of Life (QoL) Enhancing Effect of Surgery in Larynx and Hypopharynx Cancers. **Author:** Bipin T Varghese **Citation:** Indian J Surg Oncol. 2022 Dec;13(4):888–889.
12:30 pm - 12:40 pm	**Reviewer: Dr. Rakesh Taran** Identification of a seven-lncRNAs panel that serves as a prognosis predictor and contributes to the malignant progression of laryngeal squamous cell carcinoma. **Author:** Xiwang Zheng **Citation:** Front. Oncol. 13:1106249.
	Survival analyses of different treatment modalities and clinical stage for hypopharyngeal carcinoma. **Author:** Tian-Yun Lin **Citation:** Front Oncol. 2023; 13: 1109417.
12:40 pm - 01:10 pm	**PANEL DISCUSSION ON LARYNGEAL & HYPOPHYRYNGEAL CANCER**
	CHAIRPERSON: Dr. Sarbani Ghosh Laskar **MODERATOR: Dr. Deepak Balasubramanian** **PANELISTS: Dr. Kaustav Talapatra, Dr. Devang Bhavsar, Dr. Vidisha T, Dr. Minit Shah, Dr. Samir Batham, Dr. Rakesh Taran, Dr. Arjun**
01:10 pm – 02:10 pm	**BREAK**

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02:10 pm – 03:45 pm	**SESSION 4: Key Publications on Nasopharyngeal Cancer**
	CHAIRPERSONS: Dr. Kumar Prabhash
02:10 pm – 02:20 pm	**Reviewer: Dr. Minit Shah** Induction chemotherapy regimen of docetaxel plus cisplatin versus docetaxel, cisplatin plus fluorouracil followed by concurrent chemoradiotherapy in locoregionally advanced nasopharyngeal carcinoma: Preliminary results of an open-label, noninferiority, multicentre, randomised, controlled phase 3 trial. **Author:** Yan Wang **Citation:** EClinicalMedicine. 2022 Aug 27;53:101625.
	Final Overall Survival Analysis of Gemcitabine and Cisplatin Induction Chemotherapy in Nasopharyngeal Carcinoma: A Multicenter, Randomized Phase III Trial. **Author:** Yuan Zhang **Citation:** J Clin Oncol. 2022 Aug 1;40(22):2420-2425.
02:20 pm – 02:30 pm	**Reviewer: Dr. Shreyas Shelke** TIRA study: A phase III, multicenter, randomized controlled study of toripalimab plus radical chemoradiotherapy with or without concurrent cisplatin in patients with high-risk locoregionally advanced nasopharyngeal carcinoma. **Author:** Cheng Xu **Citation:** ASCO Annual Meeting 2022. Abstract TPS 6101.

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	Pembrolizumab monotherapy versus chemotherapy in platinum-pretreated, recurrent or metastatic nasopharyngeal cancer (KEYNOTE-122): an open-label, randomized, phase III trial. **Author:** A T C Chan **Citation:** Ann Oncol. 2023 Mar;34(3):251-261.
02:30 pm - 02:40 pm	**Reviewer: Dr. Anbarasan S**
	Impact of induction chemotherapy with concurrent chemoradiotherapy on nasopharyngeal carcinoma: A meta-analysis of randomized controlled trials. **Author:** Ting-Chieh Huang **Citation:** Front Oncol. 2022; 12: 965719.
	Effect of Induction Chemotherapy With Paclitaxel, Cisplatin, and Capecitabine vs Cisplatin and Fluorouracil on Failure-Free Survival for Patients With Stage IVA to IVB Nasopharyngeal Carcinoma: A Multicenter Phase 3 Randomized Clinical Trial. **Author:** Wang-Zhong Li **Citation:** JAMA Oncol. 2022 May 1;8(5):706-714.
02:40 pm - 02:50 pm	**Reviewer: Dr. Bhavesh Poladia** Adjuvant Capecitabine Following Concurrent Chemoradiotherapy in Locoregionally Advanced Nasopharyngeal Carcinoma: A Randomized Clinical Trial. **Author:** Jingjing Miao **Citation:** JAMA Oncol. 2022 Oct 13;8(12):1776-1785.

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	Induction chemotherapy regimen of docetaxel plus cisplatin versus docetaxel, cisplatin plus fluorouracil followed by concurrent chemoradiotherapy in locoregionally advanced nasopharyngeal carcinoma: Preliminary results of an open-label, noninferiority, multicentre, randomised, controlled phase 3 trial. **Author:** Yan Wang **Citation:** EClinicalMedicine. 2022 Aug 27;53:101625.
02:50 pm - 03:00 pm	**Reviewer: Dr. Vama Agarwal** NEOSPACE trial: Neoadjuvant pembrolizumab-gemcitabine-cisplatin followed by concurrent pembrolizumab-chemoradiation and maintenance pembrolizumab for stage IVA nasopharyngeal cancer (NPC). **Author:** Edwin P. Hui **Citation:** ASCO Annual Meeting 2023: Abstract:6010
	Concurrent chemoradiotherapy followed by adjuvant cisplatin-gemcitabine versus cisplatin-5-fluorouracil chemotherapy for N2-3 nasopharyngeal carcinoma: A multicentre, open-label, randomised, controlled, phase 3 trial. **Author:** Lin-Quan Tang Phd **Citation:** ASCO Annual Meeting 2023: Abstract:6000
03:00 pm - 03:10 pm	**Reviewer: Dr. Vinay Babu** Hyperfractionation compared with standard fractionation in intensity-modulated radiotherapy for patients with locally advanced recurrent nasopharyngeal carcinoma: a multicentre, randomised, open-label, phase 3 trial. **Author:** Rui You, MD **Citation:** Lancet Oncol. 2023 March;24(2):917-927.

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	Sparing Irradiation vs. Conventional Irradiation to the Medial Retropharyngeal Space in Patients with Nasopharyngeal Carcinoma: An Open-Label, Non-Inferiority, Multicenter, Randomized Phase III Trial. **Author:** Y.P. Mao **Citation:** International Journal of Radiation Oncology, Biology, Physics. Oral scientific session.S97. Abstract 279
03:10 pm - 03:15 pm	**Reviewer: Dr. Apurva Garg** The MUSES*: a prognostic study on 1360 patients with sinonasal cancer undergoing endoscopic surgery-based treatment: *MUlti-institutional collaborative Study on Endoscopically treated Sinonasal cancers. **Author:** Marco Ferrari **Citation:** Eur J Cancer. 2022 Aug;171:161-182.
03:15 pm - 03:45 pm	**PANEL DISCUSSION ON NASOPHARYNGEAL CANCER**
	CHAIRPERSONS: Dr. Mehul Bhansali **MODERATOR: Dr. Sarbani Laskar Ghosh** **PANELISTS: Dr. Bhavesh Poladia, Dr. Vinay Babu, Dr. Apurva Garg, Dr. Minit Shah, Dr. Kumar Prabhash, Dr. Vama Agarwal, Dr. Shreyas Shelke, Dr. Anbarasan S**

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03:45 pm - 04:40 pm	SESSION 5: Key Publications on Salivary gland cancer
03:45 pm - 03:55 pm	**CHAIRPERSONS: Dr. Bharat Parikh** **Reviewer: Dr. Kunal Jobanputra** Phase II Study of Enzalutamide for Patients With Androgen Receptor-Positive Salivary Gland Cancers (Alliance A091404). **Author:** Alan L Ho **Citation:** J Clin Oncol. 2022 Dec 20;40(36):4240-4249.
	Evaluation of pembrolizumab monotherapy in patients with previously treated advanced salivary gland carcinoma in the phase 2 KEYNOTE-158 study. **Author:** Caroline Even **Citation:** Eur J Cancer. 2022 Aug;171:259-268.
03:55 pm - 04:05 pm	**Reviewer: Dr. Priya P Nayak** Phase II Clinical Trial of Axitinib and Avelumab in Patients With Recurrent/Metastatic Adenoid Cystic Carcinoma. **Author:** Renata Ferrarotto **Citation:** J Clin Oncol. 2023 Mar 10;JCO2202221.
	Updated results from a phase 2 study of the oral vascular endothelial growth factor receptor 2 (VEGFR2) inhibitor rivoceranib for recurrent or metastatic (R/M) adenoid cystic carcinoma (ACC). **Author:** Hyunseok Kang **Citation:** Journal of Clinical Oncology 41(16_suppl):6040-6040

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04:05 pm - 04:10 pm	**Reviewer: Dr. Trinanjan Basu** Adjuvant radiotherapy in node-negative salivary malignancies of the parotid gland: A multi-institutional analysis. **Author:** Jung Bin Park **Citation:** Radiother Oncol. 2023 Feb 21;183:109554.
04:10 pm - 04:40 pm	**PANEL DISCUSSION ON SALIVARY GLAND CANCER**
	CHAIRPERSONS: Dr. Mehul Bhansali **MODERATOR: Dr. Pankaj Chaturvedi** **PANELISTS: Dr Kunal Jobanputra, Dr. Vishnu Agarwal, Dr. Vijay Patil, Dr. Sanjay Dudhat, Dr. Trinanjan Basu, Dr. Priya P Nayak**
04:40 pm - 04:50 pm	**BREAK**
04:50 pm - 05:50 pm	**SESSION 6: Key Publications on Thyroid Cancer**
	CHAIRPERSONS: Dr. Satish Rao
04:50 pm - 04:55 pm	**Reviewer: Dr. Rakesh Katna** Large (>4 cm) Intrathyroidal Encapsulated Well-Differentiated Follicular Cell-Derived Carcinoma Without Vascular Invasion May Have Negligible Risk of Recurrence Even When Treated with Lobectomy Alone. **Author:** Ronald Ghossein **Citation:** Thyroid. 2023 May;33(5):586-592.

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04:55 pm - 05:05 pm	**Reviewer: Dr. Praveen Shenoy** PD-L1 expression in rare and aggressive thyroid cancers: A preliminary investigation for a role of immunotherapy. **Author:** Monikongkona Boruah **Citation:** J Cancer Res Ther. 2023 Jan-Mar;19(2):312-320
	Genomic and Transcriptomic Correlates of Thyroid Carcinoma Evolution after BRAF Inhibitor Therapy. **Author:** Mark Lee **Citation:** Mol Cancer Res. 2022 Jan;20(1):45-55.
05:05 pm - 05:20 pm	**Reviewer: Dr. Manu Prasad** Anlotinib in patients with medullary thyroid carcinoma with negative prognostic factors: A sub-analysis based on the ALTER01031 study. **Author:** Jingzhu Zhao **Citation:** Front Oncol. 2022 Nov 22;12:852032.
	Phase II study of the efficacy and safety of lenvatinib for anaplastic thyroid cancer (HOPE). **Author:** Takuya Higashiyama **Citation:** Eur J Cancer. 2022 Sep;173:210-218.
	Radiotherapy and paclitaxel plus pazopanib or placebo in anaplastic thyroid cancer (NRG/RTOG 0912): a randomised, double-blind, placebo-controlled, multicentre, phase 2 trial. **Author:** Eric J Sherman **Citation:** Lancet Oncol. 2023 Feb;24(2):175-186.

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05:20 pm - 05:50 pm	**PANEL DISCUSSION ON MEDULLARY THYROID CANCER** **CHAIRPERSONS:** Dr. Shekhar Patil **MODERATOR:** Dr. Anuja Deshmukh **PANELISTS:** Dr. Nikhilesh Borkar, Dr. Archi Agarwal, Dr. Rakesh Katna, Dr. Praveen Shenoy, Dr. Manu Prasad, Dr. Aditya Joshipura, Dr. Lovin Wilson
05:50 pm - 06:55 pm	**SESSION 7: KEY PUBLICATION ON SUPPORTIVE CARE**
05:50 pm - 05:55 pm	**Reviewer:** Dr. Pradeep Ventrapathy A Randomized Controlled Trial of Cognitive Behavior Therapy to Reduce Oral Mucositis in Patients with Locoregional Advanced Nasopharyngeal Carcinoma Undergoing Chemoradiotherapy. **Author:** F. Liu **Citation:** International Journal of Radiation Oncology, Biology, Physics. Oral Scientific Session. S142. Abstract 1073.
05:55 pm - 06:05 pm	**Reviewer:** Dr. Richa Vaish Effect of Virtual Reality on Pain Management and Opioid Use Among Hospitalized Patients After Head and Neck Surgery: A Randomized Clinical Trial. **Author:** Vivek C Pandrangi **Citation:** JAMA Otolaryngol Head Neck Surg. 2022 Aug 1;148(8):724-730.

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	Effect of early interventions with manual lymphatic drainage and rehabilitation exercise on morbidity and lymphedema in patients with oral cavity cancer. **Author:** Kuo-Yang Tsai **Citation:** Medicine (Baltimore). 2022 Oct 21;101(42):e30910.
06:05 pm - 06:20 pm	**Reviewer: Dr. Suparna** Effect of Integrated Nurse-Guided Psychological Intervention on Nutritional Status of Head and Neck Cancers (HNC) Patients Undergoing Radiotherapy: A 1Randomized Controlled Study. **Author:** J. Shi **Citation:** International Journal of Radiation Oncology, Biology, Physics. Oral Scientific Session. S154. Abstract 1101.
	Impact of Nutrition Counseling in Head and Neck Cancer Sufferers Undergoing Antineoplastic Therapy: A Randomized Controlled Pilot Study. **Author:** Wangshu Dai **Citation:** Curr Oncol . 2022 Sep 26;29(10):6947-6955.
	Systematic Review of Nutrition Interventions to Improve Short Term Outcomes in Head and Neck Cancer Patients. **Author:** Claire Leis **Citation:** Cancers 2023, 15(3), 822
06:20 pm – 06:25 pm	**Reviewer: Mr. Arun Balaji** Swallowing Exercise During Head and Neck Cancer Treatment: Results of a Randomized Trial. **Author:** Sara Fredslund Hajdú **Citation:** Dysphagia . 2022 Aug;37(4):749-762.

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06:25 pm - 06:55 pm	**PANEL DISCUSSION ON SUPPORTIVE CARE** **MODERATOR: Dr. Minit Shah** **PANELISTS: Dr. Pradeep Ventrapathy, Dr. Richa Vaish, Dr. Suparna, Mr. Arun Balaji**
06:55 pm - 07:10 pm	**Break**
07:10 pm - 07:15 pm	**Introduction and welcome** **CHAIRPERSONS: Dr. Suresh H Advani**
07:15 pm - 08:00 pm	**Symposium:** Sequencing in Head and Neck Cancer in Indian patients **MODERATOR: Dr. Vijay Patil**
08:00 pm - 08:10 pm	**Cetuximab Biosimilar:** Illuminating Pathways from Bench to Patient Bedside **Speaker: Dr. M. V. Chandrakant**
08:10 pm - 08:15 pm	**Concluding Remarks** **CHAIRPERSONS: Dr. Suresh H Advani**
08:15 pm - 08:20 pm	**Vote of thanks**

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09:00 am – 10:20 pm	SESSION 8: KEY PUBLICATION ON CT + RT in Head & Neck Cancer
09:00 am - 09:10 am	**Reviewer: Dr. M. V. Chandrakanth** Cetuximab-Based vs Carboplatin-Based Chemoradiotherapy for Patients With Head and Neck Cancer. **Author:** Lova Sun **Citation:** JAMA Otolaryngol Head Neck Surg. 2022 Nov 1;148(11):1022-1028.
09:10 am - 09:20 am	**Reviewer: Dr. Akhil Kapoor** Long-Term Update of NRG/RTOG 0522: A Randomized Phase 3 Trial of Concurrent Radiation and Cisplatin With or Without Cetuximab in Locoregionally Advanced Head and Neck Cancer. **Author:** Jimmy J Caudell **Citation:** Int J Radiat Oncol Biol Phys . 2022 Dec 19;S0360-3016(22)03636-7.
	LBA5 Primary results of the phase III KEYNOTE-412 study: Pembrolizumab (pembro) with chemoradiation therapy (CRT) vs placebo plus CRT for locally advanced (LA) head and neck squamous cell carcinoma (HNSCC). **Author:** Jean-Pascal Machiels **Citation:** Annals of Oncology 33:S1399

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09:20 am - 09:35 am	**Reviewer: Dr. Gagan Saini** Phase III randomized control study evaluating adjuvant metronomic chemotherapy in locally advanced head and neck cancers post-radical chemoradiation (MACE-CTRT). **Author:** Sunil Ramdhan Chopade **Citation:** Journal of Clinical Oncology 40(16_suppl):6073-6073
09:35 am - 09:50 am	**Reviewer: Dr. Hollis Dsouza** Pembrolizumab versus cetuximab concurrent with radiotherapy in patients with locally advanced squamous cell carcinoma of head and neck unfit for cisplatin (GORTEC 2015-01 PembroRad): a multicenter, randomized, phase II trial. **Author:** Y Tao **Citation:** Ann Oncol. 2023 Jan;34(1):101-110.
	Radiotherapy with Durvalumab vs. Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer and a Contraindication to Cisplatin: Phase II Results of NRG-HN004. **Author:** Loren Mell **Citation:** International Journal of Radiation Oncology, Biology, Physics, 2022. LBA 02.
	Results of Phase III 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:** J Clin Oncol. 2023 May 1;41(13):2350-2361.

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09:50 am – 10:20 am	**PANEL DISCUSSION ON PLATINUM INELIGIBLE CT/RT**
	MODERATOR: Dr. Kumar Prabhash **PANELISTS: Dr. M. V. Chandrakanth, Dr. Akhil Kapoor, Dr. Gagan Saini, Dr. Hollis Dsouza, Dr. Pritam Kataria**
10:20 am – 10:40 am	**BREAK**
10:40 am – 11:45 pm	**SESSION 9: KEY PUBLICATION ON RECURRENT METASTATIC HEAD AND NECK CANCER**
	CHAIRPERSON: Dr. Umang Mittal
10:40 am - 10:50 am	**Reviewer: Dr. Pritam Kataria** Pembrolizumab and cabozantinib in recurrent metastatic head and neck squamous cell carcinoma: a phase 2 trial. **Author:** Nabil F. Saba **Citation:** Nat Med. 2023 Apr; 29(4): 880–887.
	Camrelizumab plus apatinib as induction therapy for locally advanced head and neck squamous cell carcinoma (IMplus): A single-arm phase II study. **Author:** Lulu Ye **Citation:** Journal of Clinical Oncology 40, no. 16_suppl (June 01, 2022) 6060-6060.
10:50 am - 11:00 am	**Reviewer: Dr. Bhuvan Chugh** Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. **Author:** Barbara Burtness **Citation:** J Clin Oncol. 2022 Jul 20;40(21):2321-2332.

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	Low-Dose Immunotherapy in Head and Neck Cancer: A Randomized Study. **Author:** Vijay Maruti Patil **Citation:** J Clin Oncol. 2023 Jan 10;41(2):222-232.
11:00 am - 11:15 am	**Reviewer: Dr. Rushab Kothari** Pembrolizumab With or Without Chemotherapy in Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma: Updated Results of the Phase III KEYNOTE-048 Study. **Author:** Kevin J Harrington **Citation:** J Clin Oncol. 2023 Feb 1;41(4):790-802.
	Nivolumab Plus Ipilimumab Versus EXTREME Regimen as First-Line Treatment for Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck: The Final Results of CheckMate 651. **Author:** Robert I Haddad **Citation:** J Clin Oncol. 2023 Apr 20;41(12):2166-2180.
	Paclitaxel with Mycidac-C in the second line and beyond in advanced head-and-neck cancer: A retrospective analysis from a tertiary cancer Center. **Author:** Rup Jyoti Sarma **Citation:** Res Stat Treat 2022;5:630-7
11:15 am - 11:45 am	**PANEL DISCUSSION ON RECURRENT NECK CANCER**
	CHAIRPERSON: Dr. Boman Dhabhar **MODERATOR: Dr. Vikram Kekatpure** **PANELISTS: Dr. V. Kannan, Dr. B K Smruti, Dr. Ashish Bakshi, Dr. Rakesh Katna, Dr. Pritam Kataria, Dr. Bhuvan Chugh, Dr. Deepak Balasubramanium, Dr. Rushab Kothari**

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11:45 am – 12:30 pm **SESSION 10: KEY PUBLICATION ON NEOADJUVANT IMMUNOTHERAPY**

11:45 am – 12:00 pm	**Reviewer: Dr. Praveen Shenoy** Preoperative durvalumab (D) with or without tremelimumab (T) for resectable head and neck squamous cell carcinoma (HNSCC): Updated results with high dimensional profiling of circulating immune cells. **Author:** Chang Gon Kim **Citation:** ASCO 2022: Abstract 6072
	Neoadjuvant nivolumab, paclitaxel, and carboplatin followed by response-stratified chemoradiation in locoregionally advanced HPV negative head and neck squamous cell carcinoma (HNSCC): The DEPEND trial. **Author:** Ari Rosenberg MD **Citation:** ASCO 2023:Abstract:6007
	Neoadjuvant toripalimab combined with gemcitabine and cisplatin in resectable locally advanced head and neck squamous cell carcinoma (NeoTGP01): An open-label, single-arm, phase Ib clinical trial. **Author:** Xiaotao Huang **Citation:** J Exp Clin Cancer Res. 2022 Oct 12;41(1):300.

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12:00 pm - 12:30 pm	**PANEL DISCUSSION ON NEOADJUVANT IMMUNOTHERAPY**
	MODERATOR: Dr. Vijay Patil **PANELISTS: Dr. Vanita Noronha, Dr. Sudhir Nair, Dr. Nandini Menon, Dr. Praveen Shenoy, Dr. Vidisha T**
12:30 pm - 01:45 pm	**SESSION 11: OTHERS (SKULL BASE, QOL, PALLIATIVE)**
12:30 pm - 12:45 pm	**Reviewer: Dr. Krishnakumar Thankappan** Surgical Strategy for Squamous Cell Carcinoma of the External Auditory Canal: Management of Locally Advanced Cases with Skull Base Involvement. **Author:** Seiya Goto **Citation:** J Neurol Surg B Skull Base. 2022 Feb 4;84(1):69-78.
	The application of salvage surgery improves the quality of life and overall survival of extensively recurrent head and neck cancer after multiple operation plus radiotherapy. **Author:** Lirui Zhang **Citation:** Front Oncol. 2022 Nov 1;12:1017630.
	Quality of Life with the Rehabilitation After Partial Mandibulectomy: a Systematic Review. **Author:** R. Kirupa Shankar **Citation:** Indian J Surg Oncol. 2023 Jun;14(2):292-300.

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12:45 pm - 12:55 pm	**Reviewer: Dr. Deepanjali Andulkar** Assessing the Prevalence of Financial Toxicity, its Predictors and Association with Health- Related Quality of Life Among Radiation Oncology Patients in India: A Cross-Sectional Patient Reported Outcome Study. **Author:** Mukhtar Ahmad Dar, PhD **Citation:** Int J Radiat Oncol Biol Phys. 2023 May 1;116(1):157-165.
	The impact of palliative radiotherapy on health-related quality of life in patients with head and neck cancer – Results of a multicenter prospective cohort study. **Author:** Marie-Luise Weiss **Citation:** Clinical and Translational Radiation Oncology.April 2023. 41(1):100633
12:55 pm - 01:05 pm	**Reviewer: Dr. Vanita Noronha** 657MO Effectiveness of geriatric assessment-driven interventions on quality of life for 2 years in older patients with head and neck cancer: Results from the EGeSOR trial. **Author:** C. Lafont **Citation:** Annals of Oncology 33:S842. Comparative Analysis of the Quality of Life in the Pretreatment of Head and Neck Cancer Patients According to Tumor Site. **Author:** Marla S. P. Cruz **Citation:** Int Arch Otorhinolaryngol 2023;27(1):e111–e116

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01:05 pm - 01:15 pm	**Reviewer: Dr. Rakesh Pinniti** Quality of life in patients with locally advanced head and neck squamous cell carcinoma undergoing concurrent chemoradiation with once-a-week versus once-every-3-weeks cisplatin. **Author:** Nandini S Menon **Citation:** Cancer Med. 2022 Nov;11(21):3939-3948.
	Dehydration Reduction in Head and Neck Cancer (DRIHNC) Trial: Daily Oral Fluid and Electrolyte Maintenance to Prevent Acute Care Clinic and Emergency Department Visits for Patients Receiving Radiation for Head and Neck and Esophageal Cancer. **Author:** Elisha Fredman **Citation:** Adv Radiat Oncol. 2022 Jul 13;7(6):101026.
01:15 pm - 01:45 pm	**PANEL DISCUSSION ON LATERAL SKULL BASE TUMORS**
	MODERATOR: Dr. Prathmesh Pai **PANELISTS: Dr. Shivakumar Thiagarajan, Dr. Krishnakumar Thankappan, Dr. Shamit Chopra, Dr. Deepanjali Andulkar, Dr. Rakesh Pinniti**
01:45 pm - 01:50 pm	**Vote of Thanks**

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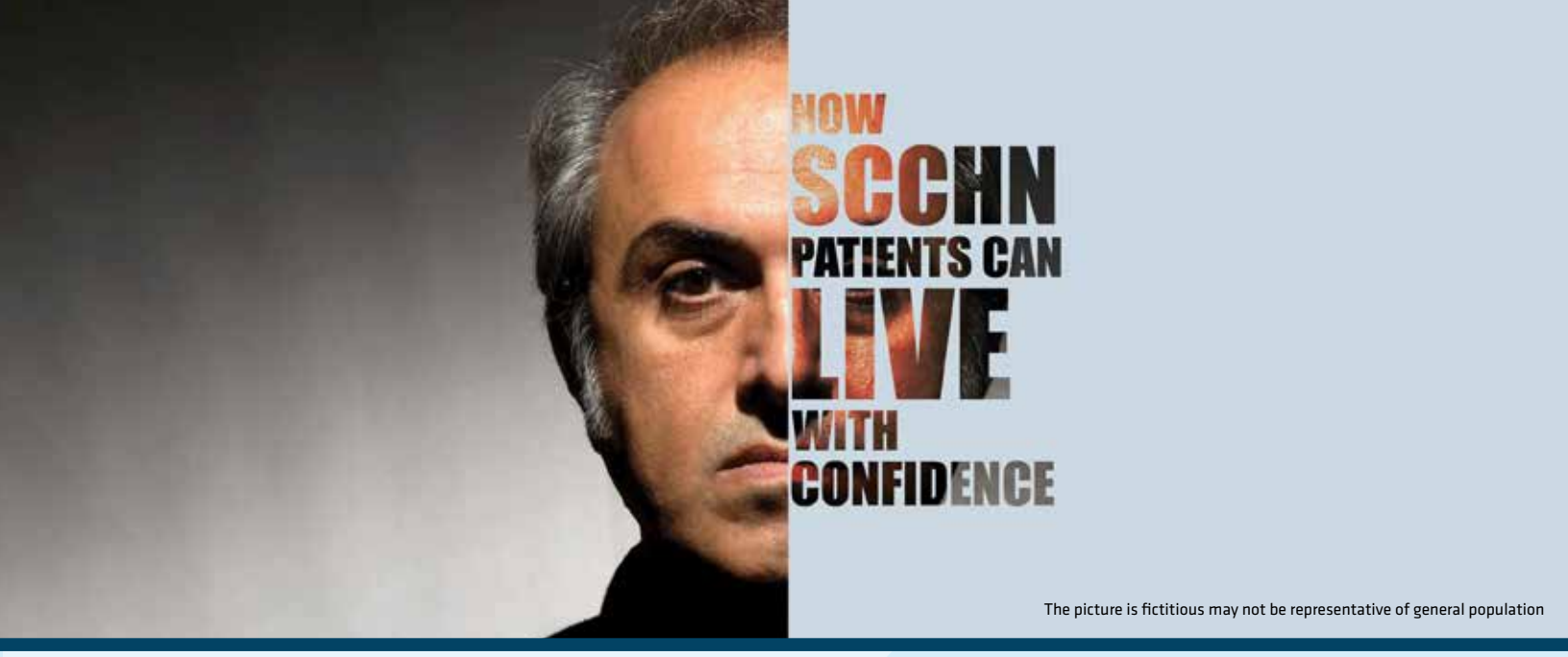

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ORR with OPDYTA®

vs

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ORR with IC

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

IC: Investigator's Choice of standard chemotherapy
*IC(cetuximab, docetaxel or methotrexate)
OS, overall survival; 1L, first line; R/M, recurrent and metastatic; AEs, adverse events, ORR, overall response rate

References:

1. Ferris RL, et al. J Oral Oncol 2018 Jun; 81: 45 - 51.
2. Sept 2016 database lock. Used with permission from Gillison et al, 2017, ASCO. Gillison M, et al. Poster presentation at ASCO 2017. 6019.

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OPDYTA® 10 mg/mL concentrate for solution for infusion.
Composition: One vial of 4 mL contains 40 mg of nivolumab; One vial of 10 mL contains 100 mg of nivolumab. **Therapeutic Indications:** Non-Small Cell Lung Cancer (NSCLC): As a single agent for the treatment of locally advanced or metastatic NSCLC after prior chemotherapy; Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. Nivolumab, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations; Renal Cell Carcinoma (RCC): As a single agent for the treatment of patients with advanced RCC after prior therapy in adults and for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab; Squamous Cell Carcinoma of the Head and Neck (SCCHN): As monotherapy for the treatment of recurrent or metastatic SCCHN after platinum-based therapy; Melanoma: As a single agent for the treatment of patients with BRAF V600 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 cHLthat 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 or Flat dosing- 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) 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. (30-minute intravenous infusion) For adjuvant treatment, the maximum duration of nivolumab is 12 months.Nivolumab in combination with fluoropyrimidine- and platinum-containing chemotherapy GC, GEJC and EAC: 360 mg Nivolumab intravenously over 30 minutes in combination fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks or 240 mg nivolumab intravenously over 30 minutes in combination with fluoropyrimidine and platinum-based chemotherapy every 2 weeks until disease progression or unacceptable toxicity. The maximum treatment duration for nivolumab is 24 months. **Nivolumab in combination with ipilimumab and platinum-based chemotherapy (NSCLC):** The recommended dose is 360 mg nivolumab administered as an intravenous infusion over 30 minutes every 3 weeks in combination with 1 mg/kg ipilimumab administered as an intravenous infusion over 30 minutes every 6 weeks, and platinum chemotherapy administered every 3 weeks. After completion of 2 cycles of chemotherapy, treatment is continued with 360 mg nivolumab administered as an intravenous infusion every 3 weeks in combination with 1 mg/kg ipilimumab every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. **Nivolumab in combination with ipilimumab (RCC):** Combination phase: nivolumab 3 mg/kg over 30 minutes every 3 weeks for the first 4 doses in combination with ipilimumab 1 mg/kg over 30 minutes, followed by the single-agent phase. Single-agent phase: 3 mg/kg every 2 weeks over 30 minutes. or 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) 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 diarrhea or colitis. Permanently discontinue nivolumab monotherapy for Grade 4 diarrhea or colitis. Immune-related hepatitis: Monitor for change in liver function. Withhold for grade 2 and permanently discontinue for grade 3 or 4 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin. Immune-related nephritis and renal dysfunction: Monitor for changes in renal function. Withhold for grade 2 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 occurence) and permanently discontinue for grade 3 myocarditis, grade 4 or recurrent grade 3, persistent grade 2 or 3 despite treatment modification, inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day. When nivolumab is administered in combination with ipilimumab, if either agent is withheld, the other agent should also be withheld. If dosing is resumed after a delay, either the combination treatment or nivolumab monotherapy could be resumed based on the evaluation of the individual patient. Complications of allogeneic hematopoietic stem cell transplant (HSCT) after Nivolumab: Monitor for transplant-related complications, including GVHD. Fatal cases have been reported in clinical studies. **Infusion reaction:** Discontinue for severe and life-threatening infusion reactions. Patients with mild or moderate infusion reaction may receive nivolumab or nivolumab in combination with ipilimumab with close monitoring and use of premedication according to local treatment guidelines. Increased mortality in patients with multiple myeloma [not an approved indication] when a PD-1 blocking antibody is added to a thalidomide analogue and dexamethasone: Treatment of patients with multiple myeloma with a PD-1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials. **Drug Interactions:** Inhibition or induction of cytochrome P450 (CYP) enzymes or other drug metabolizing enzymes by coadministered medicinal products is not anticipated to affect the pharmacokinetics of nivolumab. The use of systemic corticosteroids and other immunosuppressants at baseline, before starting nivolumab, should be avoided. However, these can be used after starting nivolumab to treat immune-related adverse reactions. **Pregnancy:** Not recommended during pregnancy and in women of childbearing potential not using effective contraception unless the clinical benefit outweighs the potential risk. Women should be advised to use effective contraception for at least 5 months following the last dose of nivolumab. Nursing Mothers: Discontinue breastfeeding. Pediatric Use: The safety and efficacy have not been established. Geriatric Use: No dose adjustment is required for elderly patients (≥65 years). Hepatic Impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Renal Impairment: No specific dose adjustment is necessary in patients with mild to moderate renal impairment. Adverse Reactions: Fatigue, rash, musculoskeletal pain, pruritus, diarrhea, nausea, cough, dyspnea, constipation, decreased appetite, back pain, arthralgia, upper respiratory tract infection, pyrexia, headache, abdominal pain, vomiting, neutropenia, hypothyroidism. Nivolumab is associated with immune-related adverse reactions. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of Nivolumab. Overdose: Closely monitor for signs and symptoms of adverse reactions and institute appropriate symptomatic treatment. Storage: Store in a refrigerator (2°C 8°C). Do not freeze.
API based on prescribing information version 14.1dated 15 Nov 2022
Issued – 16.01.2023 Before prescribing, consult full prescribing information. For further information, please contact- Bristol-Myers Squibb India Private Limited, 6th floor, Tower 1, One International Center, S.B. Marg, Elphinstone (W), Mumbai - 400013, Tel: + 91 22 6628 8600

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Reference: *Data on file

Abridged Prescribing Information

Composition: Cetuximab 100 mg/20 mL (r-DNA origin). **Solution for Intravenous Infusion in Vial | Indication:** Cetuximab is indicated for the treatment of patients with squamous cell cancer of the head and neck. **Dosage and administration:** Prior to the first infusion, patients must receive premedication with an antihistamine and a corticosteroid at least 1 hour prior to administration of cetuximab. This premedication is recommended prior to all subsequent infusions. Cetuximab is administered once a week. The initial dose is 400 mg cetuximab per m2 body surface area. All subsequent weekly doses are 250 mg cetuximab per m2 each. In patients with locally advanced squamous cell cancer of the head and neck, cetuximab is used concomitantly with radiation therapy. It is recommended to start cetuximab therapy one week before radiation therapy and to continue cetuximab therapy until the end of the radiation therapy period. In patients with recurrent and/or metastatic squamous cell cancer of the head and neck, cetuximab is used in combination with platinum-based chemotherapy followed by cetuximab as maintenance therapy until disease progression. Chemotherapy must not be administered earlier than 1 hour after the end of the cetuximab infusion. The initial dose should be given slowly and speed of infusion must not exceed 5 mg/min. The recommended infusion period is 120 minutes. For the subsequent weekly doses, the recommended infusion period is 60 minutes. The infusion rate must not exceed 10 mg/min. Paediatric population: There is no relevant use of cetuximab in the paediatric population in the granted indications. | **Contraindications:** Cetuximab is contraindicated in patients with known severe (grade 3 or 4) hypersensitivity reactions to cetuximab. Before initiation of combination treatment, contraindications for concomitantly used chemotherapeutic agents or radiation therapy must be considered. | **Adverse drug reactions:** The most undesirable effects of cetuximab are skin reactions, which occur in more than 80% of patients, hypomagnesaemia which occurs in more than 10% of patients and infusion-related reactions, which occur with mild to moderate symptoms in more than 10% of patients. Other very common to common side effects includes: - Dehydration; in particular secondary to diarrhoea or mucositis; hypocalcaemia, anorexia which may lead to weight decrease. Headache; Conjunctivitis; nausea; vomiting; Increase in liver enzyme levels (ASAT, ALAT, AP). **Warnings & Precautions:** Infusion-related, including anaphylactic, reactions - Severe infusion-related reactions, including anaphylactic reactions, may commonly occur, in some cases with fatal outcome. Occurrence of a severe infusion-related reaction requires immediate and permanent discontinuation of cetuximab therapy and may necessitate emergency treatment. Some of these reactions may be anaphylactic or anaphylactoid in nature or represent a cytokine release syndrome (CRS). A close monitoring of patients, particularly during the first administration, is required. Special attention is recommended for patients with reduced performance status and pre-existing cardio- pulmonary disease. Respiratory disorders - Cases of interstitial lung disease (ILD), including fatal cases, have been reported, with the majority of patients from the Japanese population. Confounding or contributing factors, such as concomitant chemotherapy known to be associated with ILD, and preexisting pulmonary diseases were frequent in fatal cases. Such patients should be closely monitored. In the event of symptoms (such as dyspnoea, cough, fever) or radiographic findings suggestive of ILD, prompt diagnostic investigation should occur. If interstitial lung disease is diagnosed, cetuximab must be discontinued and the patient be treated appropriately. Cardiovascular disorders- An increased frequency of severe and sometimes fatal cardiovascular events and treatment emergent deaths has been observed in the treatment of non-small cell lung cancer, squamous cell carcinoma of the head and neck and colorectal carcinoma. In some studies, association with age ≥ 65 years or performance status has been observed. When prescribing cetuximab, the cardiovascular and performance status of the patients and concomitant administration of cardiotoxic compounds such as fluoropyrimidines should be taken into account. | **Drug interactions:** In combination with platinum-based chemotherapy, the frequency of severe leukopenia or severe neutropenia may be increased. In combination with fluoropyrimidines, the frequency of cardiac ischaemia including myocardial infarction and congestive heart failure as well as the frequency of hand-foot syndrome (palmar-plantar erythrodysaesthesia) were increased compared to that with fluoropyrimidines. In combination with capecitabine and oxaliplatin, the frequency of severe diarrhoea may be increased. **Pregnancy and Lactation:** It is strongly recommended that Cetuximab be given during pregnancy or to any woman not employing adequate contraception only if the potential benefit for the mother justifies a potential risk to the foetus. It is recommended that women do not breast-feed during treatment with Cetuximab and for 2 months after the last dose, because it is not known whether cetuximab is excreted in breast milk. | **Pharmacokinetics:** When cetuximab was administered at an initial dose of 400 mg/m2 body surface area, the mean volume of distribution was approximately equivalent to the vascular space (2.9 L/m2 with a range of 1.5 to 5.2 L/m2). The mean Cmax (± standard deviation) was 185±55 mcg/mL. The mean clearance was 0.022 L/h per m² body surface area. Cetuximab has a long elimination half-life with values ranging from 70 to 100 hours at the target dose. Cetuximab serum concentrations reached stable levels after three weeks of cetuximab monotherapy. Mean peak cetuximab concentrations were 155.8 mcg/mL in week 3 and 151.6 mcg/mL in week 8, whereas the corresponding mean trough concentrations were 41.3 and 60.4 mcg/mL, respectively. In a study of cetuximab administered in combination with irinotecan, the mean cetuximab trough levels were 50.0 mcg/mL in week 12 and 40.4 mcg/mL in week 36.

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22.4

Months Longer

Progression Free Survival Benefit
was achieved vs Cisplatin RT alone

Ref: Noronha V, Patil VM, Joshi A, Mahimkar M, Patel U ,Pandey MK, et al. Nimotuzumab-cisplatin-radiation versus cisplatin-radiaation in HPV negative oropharyngeal cancer. Oncotarget. 2020 Jan 28; 11(4): 399–408

Abridged Prescribing Information:

For the use only of an Oncologist or a Hospital or a Laboratory. BIOMAb EGFR® (Nimotuzumab injection): Refer to complete prescribing information leaflet before prescribing this product. Further information is available upon request. Composition: BIOMAb EGFR® Each 10mL vial contains: Nimotuzumab 50.0mg (Humanized anti EGFR monoclonal antibody), Sodium phosphate dibasic 18.0mg, Sodium phosphate monobasic 4.5mg, Sodium chloride 86.0mg, Polysorbate 80 2.0mg and Water for injection qs 10mL. Indications: Nimotuzumab is indicated for use in the treatment of advanced Squamous Cell Carcinoma of Head and Neck region with concurrent chemotherapy and/ or radiotherapy. Dosage and Administration: Nimotuzumab is administered as continuous intravenous (IV) infusions in weekly doses of 200mg for 6 weeks, in combination with a standard radiotherapy and/ or chemotherapy for head and neck cancers. 200mg of the antibody is diluted in 250mL of sodium chloride and infused over 60 minutes. During dilution with normal saline ensure that all precautions are taken to avoid accidental contamination. In case of any turbidity being seen in the solution it is due to accidental microbial contamination. In such case please discard the solution and prepare a fresh solution. Contraindications: None known. Warnings and Precautions: BIOMAb EGFR® should be used with caution in patients with known hypersensitivity to Nimotuzumab or to any of the known components of the formulation. Use in Pregnancy and Lactation: Human IgG1 is known to cross the placental barrier; but it is not known whether the antibody can cause fetal harm when administered to a pregnant woman. The antibody should only be given to a pregnant woman, or any woman not employing adequate contraception if the potential benefit outweighs the potential risk to the fetus. If the patient becomes pregnant while receiving this drug, she should be informed of the potential hazard to the fetus and/or the potential risk for loss of the pregnancy. Since human IgG1 is secreted in human milk, the potential for absorption and harm to the infant after ingestion is unknown. No recommendation is made on the potential benefit versus risk of administering Nimotuzumab to nursing mothers. Undesirable Effects: During clinical trials in patients with head and neck cancers, where Nimotuzumab was used concurrently with or without radiotherapy and/or chemotherapy; the commonly reported adverse events in the radiotherapy group were fever, chills, mucositis, pruritis, urticaria/rash, headache, hypertension and fluctuation in blood pressure. The reported adverse events in the chemo radiotherapy group were mucositis, asthenia, dizziness, haematuria (microscopic), vomiting and loose stools. Only rash and chills was rated by the investigator as certainly related to Nimotuzumab. Anaphylactic skin reaction was the only serious adverse event (SAE) reported due to Nimotuzumab, others were due to the underlying malignant disorder or as a result of treatment with concurrent chemotherapy or radiotherapy. In another clinical trial on advanced nasopharyngeal squamous carcinoma, the most frequently observed adverse reactions include low fever, hypotension, nausea, dizziness and skin rash. Adverse reactions observed in clinical trials when Nimotuzumab was used along with radiotherapy for the treatment of advanced epidermal derived tumors in head and neck cancers, were fever, tremors, nausea and vomiting, chills, hypotension, weakness, headache, anaemia and acral cyanosis. Most of the AEs reported during the trials when Nimotuzumab was combined with radiotherapy were associated with radiation; whereas nausea and fatigue were the most commonly reported non-radiation associated AEs. Irradiation toxicity was not exacerbated by the addition of Nimotuzumab to standard radiotherapy. Presentation: Available as single carton of 4 vials and each vial of 10mL (50.0 mg of Nimotuzumab).

Manufactured By: Biocon Limited, Special Economic Zone, Plot No. 2-4, Phase IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bangalore – 560 099, India. Marketed By: Biocon Limited, 20th K.M., Hosur Road, Electronics City, Bangalore – 560100, India. Visit our website www.biocon.com or call toll free number: 1800 102 9465 or e-mail us at drugsafety@biocon.com