

OrigAMI-5: A randomized, phase 3 study of subcutaneous amivantamab plus pembrolizumab and carboplatin vs standard of care pembrolizumab plus platinum and 5-fluorouracil as first-line treatment in recurrent/metastatic head and neck cancer

Robert I Haddad¹, Renata Ferrarotto², Ye Guo³, Kevin J Harrington⁴, Lisa Licitra⁵, Nabil F Saba⁶, Makoto Tahara⁷, Pablo Nenclares⁸, Irene Braña⁹, John Xie¹⁰, Pei-Ling Chu¹⁰, Mariah Ennis¹¹, Jessica Dobbs¹², Brooke Diorio¹¹, Priya Kim¹³, Sujay Shah¹³, Barbara Burtness¹⁴

¹Dana-Farber Cancer Institute, Boston, MA, USA; ²The University of Texas MD Anderson Cancer Center, Houston, TX, USA; ³Shanghai East Hospital, Shanghai, China; ⁴The Institute of Cancer Research/Royal Marsden Hospital, London, UK; ⁵Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; ⁶Winship Cancer Institute, Emory University, Atlanta, GA, USA; ⁷National Cancer Center Hospital East, Kashiwa, Japan; ⁸The Institute of Cancer Research/Royal Marsden NHS Foundation Trust, London, UK; ⁹Vall d' Hebron Institute of Oncology (VHIO), Barcelona, Spain; ¹⁰Johnson & Johnson, Raritan, NJ, USA; ¹¹Johnson & Johnson, Titusville, NJ, USA; ¹²Johnson & Johnson, Bridgewater, NJ, USA; ¹³Johnson & Johnson, Spring House, PA, USA; ¹⁴Yale School of Medicine/Yale Cancer Center, New Haven, CT, USA



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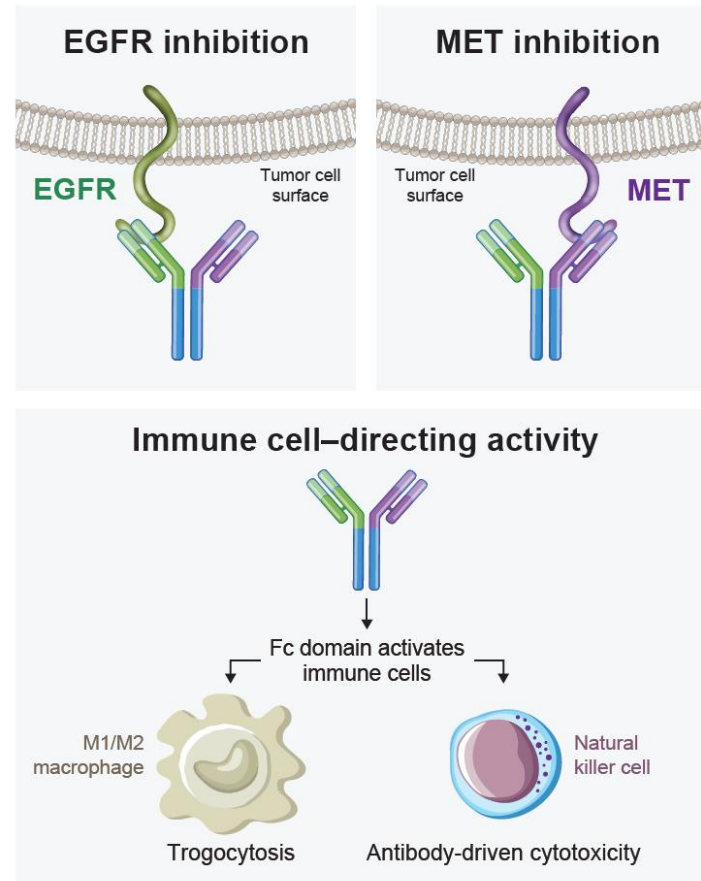
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BACKGROUND

- R/M HNSCC is associated with significant morbidity and mortality^{1,2}
- Current first-line standard-of-care regimens, including combinations of pembrolizumab with or without platinum-based chemotherapy and 5-FU, yield low response rates and poor long-term outcomes, with a median survival of ~1 year³
- Many p16-negative HNSCC tumors exhibit EGFR and MET overexpression^{4,5}
- Amivantamab is an EGFR-MET bispecific antibody with immune cell–directing activity (**Figure 1**)^{6,7} and has demonstrated meaningful activity across several solid tumor types^{8–10}
- In prior reports of the phase 1b/2 OrigAMI-4 study (NCT06385080):
 - Subcutaneous amivantamab monotherapy demonstrated a confirmed investigator-assessed ORR of 47% in R/M HNSCC after immune checkpoint inhibitor and platinum-based chemotherapy⁸
 - Among previously untreated R/M HNSCC, subcutaneous amivantamab plus pembrolizumab demonstrated a confirmed ORR of 56%¹¹

Figure 1: Amivantamab's MoA¹²



5-FU, 5-fluorouracil; EGFR, epidermal growth factor receptor; MoA, mechanism of action; ORR, objective response rate; R/M HNSCC, recurrent and/or metastatic head and neck squamous cell cancer.



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FIGURE 1 Amivantamab's MOA

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OBJECTIVE

This global, randomized, phase 3 study is evaluating the efficacy and safety of subcutaneous amivantamab in addition to pembrolizumab and carboplatin, as compared with the standard of care (pembrolizumab plus carboplatin or cisplatin and 5-FU), as first-line therapy for participants with R/M HNSCC

5-FU, 5-fluorouracil; R/M HNSCC, recurrent and/or metastatic head and neck squamous cell cancer.

Solid Tumors



Presented by RI Haddad at the American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL, USA.

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METHODS

- OrigAMI-5 is a randomized, open-label, phase 3 study currently recruiting participants with R/M HNSCC (**Figure 2**)
 - Primary tumor locations of oral cavity, hypopharynx, larynx and HPV-negative oropharyngeal cancer are eligible
 - HPV-positive oropharyngeal cancer and any known HPV positivity are excluded
- Participants will be randomized 1:1 to receive subcutaneous amivantamab with pembrolizumab and carboplatin, or 5-FU plus pembrolizumab and investigator's choice of carboplatin or cisplatin

5-FU, 5-fluorouracil; HPV, human papillomavirus; R/M HNSCC, recurrent and/or metastatic head and neck squamous cell cancer.



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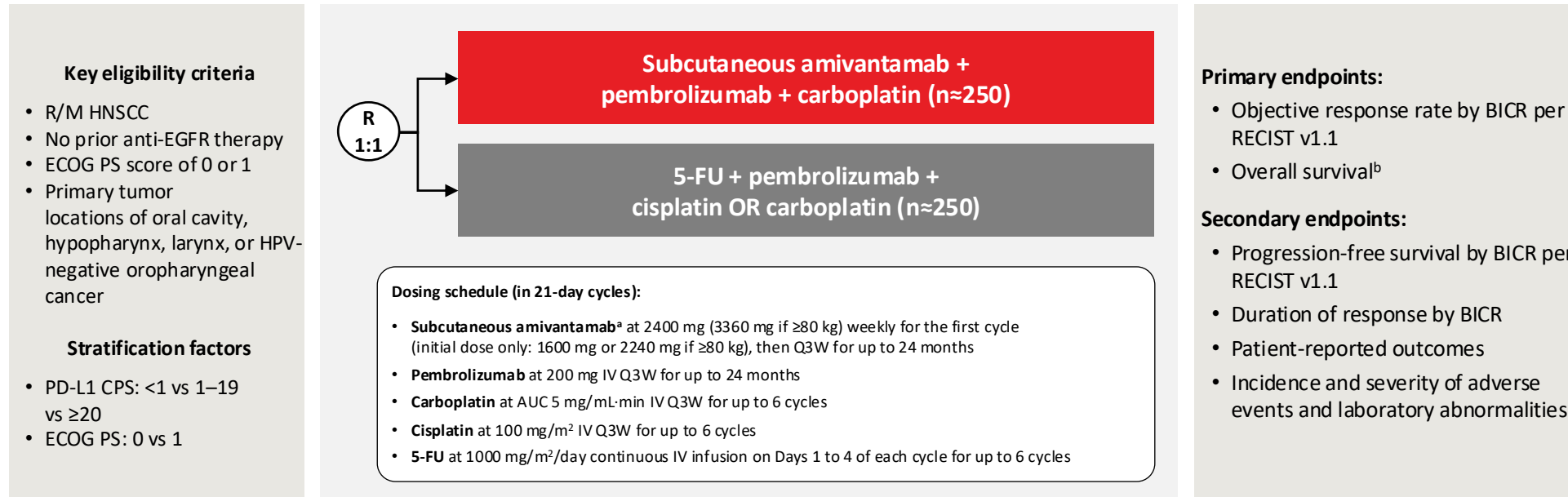
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Figure 2: OrigAMI-5 study design



^aCoformulated with recombinant human hyaluronidase PH20 (rHuPH20). ^bFor the European Union and any applicable country/region, the primary endpoint is overall survival only.

5-FU, 5-fluorouracil; AUC, area under the curve; BICR, blinded independent central review; CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; HNSCC, head and neck squamous cell cancer; HPV, human papillomavirus; IV, intravenous; PD-L1, programmed death ligand 1; Q3W, every 3 weeks; R, randomized; R/M, recurrent/metastatic; RECIST v1.1, Response Evaluation Criteria in Solid Tumors v1.1.



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- Key inclusion and exclusion criteria are shown in **Table 1**

Table 1: Key inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• Histologically or cytologically confirmed R/M HNSCC• Primary sites limited to oral cavity, hypopharynx, larynx, and HPV-negative oropharyngeal cancer• No prior systemic therapy for R/M disease; prior curative-intent therapy allowed if completed >6 months prior without early progression• ECOG PS score of 0 or 1• PD-L1 CPS determined locally using validated testing within 6 months prior (for stratification; positivity not required for enrollment)	<ul style="list-style-type: none">• Any prior anti-EGFR or anti-MET therapy in any setting• Any known HPV positivity• Untreated brain metastases or leptomeningeal disease; treated brain metastases allowed only if clinically stable and off steroids (≤ 10 mg prednisone or equivalent)• Current or prior ILD, pneumonitis, or pulmonary fibrosis• Uncontrolled illness, including (not limited to) ongoing or active infection

CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; HNSCC, head and neck squamous cell cancer; HPV, human papillomavirus; ILD, interstitial lung disease; PD-L1, programmed death ligand 1; R/M, recurrent/metastatic.



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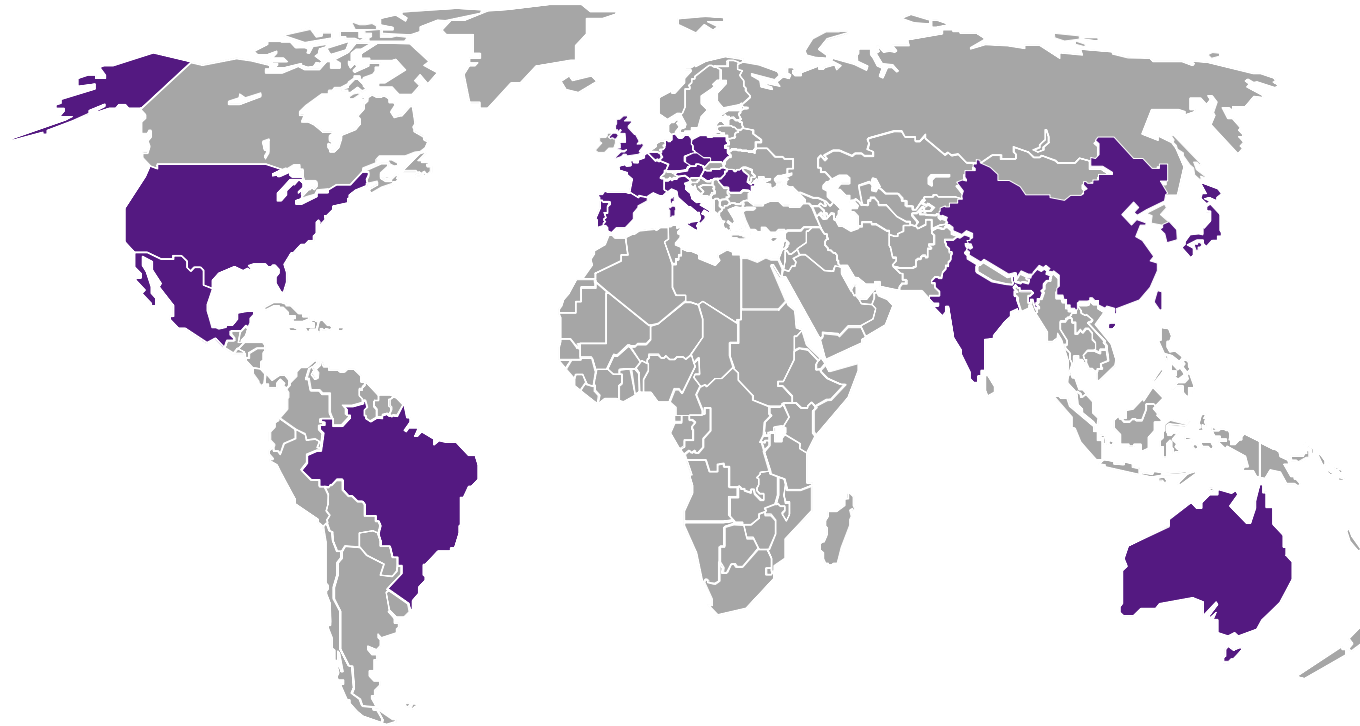
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- The multicenter, global OrigAMI-5 study is planned to open at approximately 205 sites across 22 countries (Figure 3)

Figure 3: Participating countries



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SUMMARY



OrigAMI-5 is a global, randomized, phase 3 study evaluating amivantamab plus pembrolizumab and carboplatin versus standard of care (pembrolizumab plus carboplatin or cisplatin and 5-FU) as first-line therapy for participants with R/M HNSCC

5-FU, 5-fluorouracil; R/M HNSCC, recurrent and/or metastatic head and neck squamous cell cancer.

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CURRENT STATUS AND REGISTRATION INFORMATION

- ✓ **Current status:**
OrigAMI-5 is currently enrolling, with a goal of approximately 500 participants
- ✓ **Registration information:**
This study is registered with ClinicalTrials.gov (Identifier: NCT07276399)

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