Amivantamab in recurrent/metastatic head & neck squamous cell cancer after immune checkpoint inhibitor and chemotherapy: pivotal results from the phase 1b/2 OrigAMI-4 study

Barbara Burtness[1], Kevin J Harrington[2], Dongmei Ji[3], Benoit Calderon[4], Sun Min Lim[5], Muh-Hwa Yang[6], Shau-Hsuan Li[7], Shigenori Kadowaki[8], Paul L Swiecicki[9], Jessica L Geiger[10], William Ince[11], Dennis Hahn[12], Ye Guo[13], Douglas Adkins[14], Joshua C Curtin[15], Kiichiro Toyoizumi[16], Mark S Wade[15], Emrullah Yilmaz[17], Priya Kim[15], Ari J Rosenberg[18]

[1]Yale Cancer Center, Yale School of Medicine, New Haven, CT, USA; [2]The Institute of Cancer Research/Royal Marsden Hospital, London, UK; [3]Department of Head & Neck Tumors and Neuroendocrine Tumors, Fudan University Shanghai Cancer Center, Shanghai, China; [4]Institut Sainte Catherine, Avignon, France; [5]Division of Medical Oncology, Department of Internal Medicine, Yonsei Cancer Center, Severance Hospital, Yonsei University Health System, Seoul, Republic of Korea; [6]Division of Medical Oncology, Department of Oncology, Taipei Veterans General Hospital, Taipei, Taiwan; [7]Department of Hematology-Oncology, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine, Kaohsiung, Taiwan; [8]Department of Clinical Oncology, Aichi Cancer Center Hospital, Nagoya, Japan; [9]Division of Hematology/Oncology, Department of Internal Medicine, University of Michigan Rogel Cancer Center, Ann Arbor, MI, USA; [10]Department of Hematology and Medical Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH, USA; [11]Addenbrooke's Hospital, Cambridge, UK; [12]Department of Hematology, Oncology, Stem-Cell Transplantation, and Palliative Care, Klinikum Stuttgart, Stuttgart, Germany; [13]Department of Oncology, Shanghai East Hospital, School of Medicine, Tongji University, Shanghai, China; [14]Washington University School of Medicine, Robert Ebert and Greg Stubblefield Head and Neck Tumor Center, Alvin J Siteman Cancer Center, and Barnes Jewish Hospital, St Louis, MO, USA; [15]Johnson & Johnson, Spring House, PA, USA; [16]Johnson & Johnson, Tokyo, Japan; [17]Johnson & Johnson, Raritan, NJ, USA; [18]Department of Medicine, Section of Hematology and Oncology, University of Chicago, Chicago, IL, USA

WHAT DO THESE RESULTS MEAN FOR INDIVIDUALS WITH HEAD & NECK SQUAMOUS CELL CANCER (HNSCC)?

Subcutaneous (injected under the skin) amivantamab helped shrink tumors in individuals with recurrent or metastatic (R/M) HNSCC who had previously received immunotherapy and platinum-based chemotherapy. Responses to subcutaneous amivantamab lasted a long time and occurred quickly

WHAT WAS THE PURPOSE OF THIS STUDY?

- In this study, researchers aimed to find out how well subcutaneous amivantamab works for treating individuals with R/M HNSCC who had previously received a type of immunotherapy, called an immune checkpoint inhibitor, and platinum-based chemotherapy

WHO WAS IN THE STUDY AND HOW WAS IT CARRIED OUT?

- OrigAMI-4 (NCT06385080) is a phase 1b/2 study evaluating subcutaneous amivantamab alone or in addition to standard-of-care therapies in participants with R/M HNSCC
- Cohort 1 of the study included participants with R/M HNSCC who had previously received an immune checkpoint inhibitor and platinum-based chemotherapy
- The main goal of the study was to assess the objective response rate (ORR)

Figure 1: Study design and participant characteristics

All participants:
- ✓ Have R/M HNSCC
- ✓ Have an ECOG PS score of 0 or 1
- ✓ Have not previously received anticancer therapy that targets the EGFR receptor

102 participants were included in this analysis → Subcutaneous amivantamab was injected into the abdomen every 3 weeks →

Outcomes evaluated

Primary endpoint:
- ORR

Other endpoints:
- Duration of response
- Clinical benefit rate
- PFS
- OS
- Safety

63 years Median age

77% were male

47% had oral cavity as the primary tumor location

ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; HNSCC, head & neck squamous cell cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R/M, recurrent or metastatic.

WHAT WERE THE RESULTS?

Participants who received subcutaneous amivantamab had their tumors shrink quickly, and this response lasted a long time. Side effects with subcutaneous amivantamab were generally manageable, and no new side effects were observed compared with the previous analysis[1]

Figure 2: Responses to subcutaneous amivantamab

42% Confirmed ORR →

- **15%** Participants whose signs of cancer disappeared
- **27%** Participants whose cancer shrank but did not disappear

ORR, objective response rate.

Figure 3: Time to and duration of responses

6.6 weeks Median time to see first effects on the tumor

Among the 43 participants whose tumors were affected by the treatment:

- **56%** had a response to the treatment for **≥6 months**
- **63% had an ongoing response** at the time of the analysis

Figure 4: Survival outcomes

At a median follow-up of **11.8 months**:

Median amount of time participants were alive without the cancer growing further: **6.8 months**

Median amount of time participants were alive: **12.5 months**

Figure 5: Common side effects with subcutaneous amivantamab

- **37%** Rash
- **34%** Acne-like skin rash
- **34%** Nail infection/inflammation
- **28%** Sores in the mouth
- **50%** Low albumin in the blood
- **24%** Swelling in arms or legs

Glossary of terms

ECOG PS	A rating scale used to assess the effect a patient's disease has on daily activities; a score of 0 or 1 shows good daily functioning	**Immune checkpoint inhibitor**	A type of drug that helps the immune system attack cancer cells	**Median PFS**	The middle value of time participants are alive without the cancer growing further	**Recurrent or metastatic**	Cancer that has come back or spread
EGFR and MET	Proteins that relay chemical signals that tell the cell to grow, divide, spread, and survive	**Median OS**	The middle value of time participants are alive after starting treatment	**ORR**	The percentage of participants whose cancer shrank or disappeared after treatment	**Subcutaneous**	Injected under the skin

REFERENCE: 1. Harrington KJ, et al. *Oral Oncol.* 2025;171:107791.

Scan the QR code for the full presentation

*AI was used in the preparation of these summaries.