## Transcript Details

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# Amivantamab Monotherapy or in Combination With Paclitaxel in Previously Treated Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma: OrigAMI-4 Study Results

**Announcer:**
Welcome to DataPulse from ESMO 2025 on ReachMD. This activity, titled “Amivantamab Monotherapy or in Combination With Paclitaxel in Previously Treated Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma: OrigAMI-4 Study Results” is provided by Prova Education.

**Dr. Harrington:**
Hello. My name is Kevin Harrington. I'm professor in biological cancer therapies at the Institute of Cancer Research in London. Today I'm speaking to you from ESMO 2025 in Berlin, and I have great pleasure in discussing with you two abstracts relating to the use of amivantamab in patients with relapsed and/or metastatic squamous cell carcinoma of the head and neck.

Now, amivantamab is a bifunctional antibody that targets both EGFR and cMET. There is a strong rationale for using this agent in relapsed metastatic head and neck cancer—first, by virtue of blockade of EGFR, mediating the effect against the tumor; second, blockade of cMET potentially prevents resistance mechanisms to EGFR-targeted therapies; and the third putative mechanism is through recruitment of immune cells to the tumor.

This agent has been tested and has been reported at this meeting in two contexts. So the first that I would like to discuss with you is the use of amivantamab as a monotherapy in HPV-unrelated head and neck cancer, and this represents data from Cohort 1 of the phase 1b/2 OrigAMI-4 study.

So in this study, patients with relapsed head and neck cancer of good performance status and good organ function, with HPV-unrelated disease, were allocated to receive single-agent amivantamab as a subcutaneous formulation on a 3-weekly schedule.

We presented data on two groups of patients. So there was the population of patients available for safety analysis and that comprised 86 patients, and a population of patients for efficacy evaluation of 38 patients.

So in terms of safety, for those patients who had received at least one dose of the drug, we showed that this drug was extremely tolerable. We saw the anticipated side effects of EGFR blockade—notably skin and nail changes—and also hypomagnesemia. And for the cMET component, we saw peripheral edema and hypoalbuminemia. These were manageable. Notably, for infusion-related reactions with the subcutaneous formulation, we only saw 7% infusion-related reactions, and none of those was greater than grade 2.

When we turned to the efficacy-evaluable population of 38 patients, we reported an overall response rate of 45%, with a further 45% demonstrating stable disease. 82% of patients showed shrinkage of some of their tumor lesions, and a substantial proportion of patients continue ongoing on treatment at the time of this data cut.

This agent has shown significant activity in this disease, and as a consequence of this study, we have seen that amivantamab has moved forward now into planning for a phase 3 trial—the OrigAMI-5 study—which will evaluate amivantamab plus pembrolizumab and carboplatin versus the standard of care treatment of chemotherapy plus pembrolizumab from the KEYNOTE-048 study.

Now, in the second cohort of patients that were presented at this meeting, we looked at Cohort 3 from the OrigAMI-4 study. This cohort of patients received amivantamab in combination with paclitaxel. The amivantamab schedule was as described previously. The paclitaxel was at 175 mg/m$^2$ every 3 weeks.

In this relatively small cohort of 11 patients, we saw 7 responders, 4 of whom were ongoing at the time of the analysis. This is a 64% response rate. Treatment was tolerable. DLT occurred in a single patient with events of mucositis and fatigue, both of which resolved. The selected recommended phase 2 dose level was the dose level zero—the entry dose of the study.

So in summation, what we have seen in these two abstracts is evidence that amivantamab, either as a single agent or in combination with chemotherapy, has substantial activity in patients with relapsed metastatic head and neck cancer. We have seen clear evidence and a rationale for developing this agent further, and indeed for bringing this agent now into the first-line setting. We look forward to the further development of this agent for the benefit of our patients.

I'm Kevin Harrington, and I'm speaking to you from ESMO 2025 in Berlin, and I thank you very much for your attention.

**Announcer:**
Thank you for listening to this DataPulse from ESMO 2025 on ReachMD. This activity is provided by Prova Education. Thank you for listening.