

Genmab Announces Statistically Significant, Clinically Meaningful Improvement in Overall Survival and Objective Response with Petosemtamab Combination at First Interim Analysis in First-Line R/M Patients with PD-L1+ Head and Neck Cancer

Company Announcement

COPENHAGEN, Denmark; October 28, 2026

- **Phase 3 LiGeR-HN1 trial of Petosemtamab in combination with pembrolizumab versus pembrolizumab alone met both primary endpoints, reducing the risk of death by 50% in patients with PD-L1 positive head and neck squamous cell carcinoma (HNSCC), regardless of HPV status**
- **Genmab plans to engage global regulatory authorities and will submit full results for presentation at a future medical meeting**

Genmab A/S (Nasdaq: GMAB) today announced positive topline results from the global Phase 3 LiGeR-HN1 trial ([NCT06525220](#)) evaluating petosemtamab, an investigational IgG1-bispecific antibody targeting the epidermal growth factor receptor (EGFR) and the leucine-rich repeat containing G-protein-coupled receptor 5 (LGR5), in combination with pembrolizumab versus pembrolizumab in patients with first-line (1L) PD-L1 positive recurrent/metastatic head and neck squamous cell carcinoma (HNSCC). Based on the first interim analysis assessed by an independent data monitoring committee (IDMC), treatment with the petosemtamab combination demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS), reducing the risk of death by 50%, and objective response rate (ORR) versus pembrolizumab [OS: HR 0.50 (95% CI, 0.37, 0.67); $p < 0.0001$; ORR: odds ratio 3.17 (95% CI, 2.06, 4.89; $p < 0.0001$), meeting its dual primary endpoints, regardless of HPV status.

The safety profile of petosemtamab when administered in combination with pembrolizumab was generally well tolerated and consistent with the previously reported safety profiles of the individual agents (petosemtamab and pembrolizumab). No new safety signals were identified.

“Patients with recurrent or metastatic head and neck cancer face a disease that can profoundly affect both survival and some of the most essential aspects of daily life, making progress in treatment urgently needed. As the first positive Phase 3 study in this patient population in several years, LiGeR-HN1 represents a major milestone with the potential to redefine care,” said Everett E. Vokes, MD, Chair, Department of Medicine and Physician-in-Chief, University of Chicago Medicine. “Meeting its dual primary endpoints of overall survival and objective response rate at the first interim analysis underscores the potential of petosemtamab plus pembrolizumab to transform first-line treatment for patients with PD-L1-positive disease, regardless of HPV status. These results suggest this chemotherapy-free combination could reshape the treatment of this devastating disease by establishing a new therapeutic option.”

“These topline Phase 3 results represent a defining milestone for Genmab and further strengthen our conviction in petosemtamab as a potential first-in-class treatment option for patients with this difficult-to-treat cancer,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “Meaningful innovation is measured not only by scientific discovery, but by its potential to improve outcomes for patients. The LiGeR-HN1 topline findings mark an important step toward potentially bringing petosemtamab to patients with recurrent or metastatic head and neck cancer, and we look forward to engaging with regulatory authorities globally and sharing the full dataset with the medical community.”

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Based on these positive topline results, Genmab plans to engage global regulatory authorities and will submit the full results from LiGeR-HN1 for presentation at a future medical meeting.

Beyond LiGeR-HN1, petosemtamab is being evaluated in multiple Phase 3 trials, including LiGeR-HN2 ([NCT06496178](#)) in patients with second- and third-line recurrent/metastatic HNSCC, and two Phase 3 studies, LiGeR-CRC1 ([NCT07702032](#)) and LiGeR-CRC2 ([NCT07775287](#)), in patients with previously treated, recurrent, unresectable or metastatic colorectal cancer.

On Wednesday, October 28 at 5:00 p.m. CET/12:00 p.m. EDT, Genmab will host an investor update. To register, visit genmab.com/events-presentations.

About the LiGeR-HN1 Trial (NCT06525220)

LiGeR-HN1 ([NCT06525220](#)) is a randomized, open-label, global, multicenter Phase 3 study evaluating the efficacy and safety of petosemtamab plus pembrolizumab vs pembrolizumab in first-line treatment of recurrent or metastatic PD-L1+ HNSCC. Patients are randomized 1:1 to receive either petosemtamab plus pembrolizumab or pembrolizumab alone. The study's co-primary endpoints are overall survival (OS) and objective response rate (ORR). Key secondary endpoints include progression-free survival, duration of response, time to response, safety and patient-reported outcomes.

About Head and Neck Squamous Cell Carcinoma

Head and Neck Squamous Cell Carcinoma (HNSCC) is a group of biologically similar cancers that arise from the tissue lining the surfaces of the oral cavity, pharynx and larynx and represent more than 90% of all head and neck cancers.ⁱ It is the seventh most common cancer globally.ⁱⁱ Risk for HNSCC is approximately two to four times higher in men than women.ⁱⁱⁱ Treatment options vary depending on individual factors, including the location of the tumor, stage of the tumor and a person's overall health.ⁱⁱⁱ Despite current treatment options, there remains a high patient need for additional therapies, as approximately 50% of patients with locally advanced HNSCC will experience disease recurrence following initial treatment. Recurrent or metastatic HNSCC is associated with a median overall survival of approximately 10-12 months.^{iv}

About Petosemtamab (GEN1158)

Petosemtamab is an investigational low-fucose, fully human immunoglobulin G1 (IgG1) bispecific antibody with an active Fc domain that binds to EGFR and LGR5 on tumor cells. LGR5 is expressed on a population of cancer stem-like cells implicated in tumor initiation, treatment resistance, and recurrence. Petosemtamab exerts anti-tumor activity through three distinct and complementary mechanisms. Binding to EGFR blocks ligand binding and inhibits EGFR signaling functions regardless of LGR5 expression. In tumor cells co-expressing LGR5 and EGFR, simultaneous binding to LGR5 and EGFR enables degradation of EGFR through the natural internalization process of LGR5. In addition, engagement with tumor cells facilitates their destruction by innate immune cells, such as natural killer (NK) cells, through antibody-dependent cell-mediated cytotoxicity (ADCC). Petosemtamab is currently being evaluated for the potential treatment of head and neck squamous cell carcinoma (HNSCC) and other solid tumors, including metastatic colorectal cancer (mCRC). The safety and efficacy of petosemtamab have not been established. Petosemtamab has received U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation for the first-line treatment of patients with recurrent or metastatic PD-L1-positive HNSCC in combination with pembrolizumab and for the treatment of patients with recurrent or metastatic

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HNSCC whose disease has progressed following platinum-based chemotherapy and anti-PD-1 therapy. Please visit <https://clinicaltrials.gov/> for more information.

About Genmab

Genmab is an international biotechnology company dedicated to improving the lives of people with cancer and other serious diseases through innovative antibody medicines. For over 25 years, its passionate, innovative and collaborative team has advanced a broad range of antibody-based therapeutic formats, including bispecific antibodies, ADCs, immune-modulating antibodies and other next-generation modalities. Genmab's science powers eight approved antibody medicines, and the company is advancing a strong late-stage clinical pipeline, including wholly owned programs, with the goal of delivering transformative medicines to patients.

Established in 1999, Genmab is headquartered in Copenhagen, Denmark, with international presence across North America, Europe and Asia Pacific. For more information, please visit [Genmab.com](https://www.genmab.com) and follow us on [LinkedIn](#) and [X](#).

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This Company Announcement contains forward looking statements. The words "believe," "expect," "anticipate," "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with preclinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products or technologies obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

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ⁱ Johnson DE, Burtress B, Leemans CR, Lui VWY, Bauman JE, Grandis JR. "Head and neck squamous cell carcinoma." *Nat Rev Dis Primers*, 2020 Nov 26;6(1):92. doi: 10.1038/s41572-020-00224-3. Erratum in: *Nat Rev Dis Primers*. 2023 Jan 19;9(1):4. doi: 10.1038/s41572-023-00418-5. PMID: 33243986; PMCID: PMC7944998.

ⁱⁱ Barsouk A, Aluru JS, Rawla P, Saginala K, Barsouk A. "Epidemiology, Risk Factors, and Prevention of Head and Neck Squamous Cell Carcinoma." *Med Sci (Basel)*, 2023 Jun 13;11(2):42. doi: 10.3390/medsci11020042. PMID: 37367741; PMCID: PMC10304137.

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ⁱⁱⁱ Cancer Research Institute. "Head and Neck Cancer a Promising Treatment?" Accessed June 4, 2026.

<https://www.cancerresearch.org/immunotherapy-by-cancer-type/head-and-neck-cancer>.

^{iv} Ionna F, Bossi P, Guida A, Alberti A, Muto P, Salzano G, Ottaiano A, Maglitter F, Leopardo D, De Felice M, Longo F, Tafuto S, Della Vittoria Scarpati G, Perri F. "Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck: A Big and Intriguing Challenge Which May Be Resolved by Integrated Treatments Combining Locoregional and Systemic Therapies." *Cancers (Basel)*, 2021 May 14;13(10):2371. doi: 10.3390/cancers13102371. PMID: 34069092; PMCID: PMC8155962.