

Genmab Announces Updated Follow-Up Analyses from Phase 2 Study of Petosemtamab Demonstrate Meaningful Objective Response Rates in Patients with Metastatic Colorectal Cancer

Media Release

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- **Petosemtamab demonstrates encouraging objective response rates (ORRs), with promising depth and durability of response, in first- and second-line metastatic colorectal cancer (mCRC)**
- **Data reinforces the ongoing global Phase 3 trials of petosemtamab in mCRC, which are actively enrolling patients**

Genmab A/S (Nasdaq: **GMAB**) today announced updated follow-up analyses from a Phase 2 trial evaluating petosemtamab, an investigational IgG1-bispecific antibody targeting the epidermal growth factor receptor (EGFR) and leucine-rich repeat containing G-protein-coupled receptor 5 (LGR5), in combination with FOLFOX or FOLFIRI in patients with metastatic colorectal cancer (mCRC). At a median follow-up of 5.9 months in the first-line (1L) setting and 7.1 months in the second-line (2L) setting, confirmed and unconfirmed objective response rates (ORRs) were 75% and 67%, respectively, with an ORR of 81% observed among 1L patients with left-sided tumors. With longer follow-up, most of the previously unconfirmed objective responses were subsequently confirmed, reinforcing the consistency of the clinical activity observed across treatment settings. The updated analyses reinforce the depth and durability of responses observed in both 1L and 2L treatment settings and support the ongoing global Phase 3 development program. The findings were presented at the European Society for Medical Oncology (ESMO) Congress 2026, held in Madrid, Spain.

“Despite advances in the treatment of metastatic colorectal cancer, outcomes remain poor for many patients once disease has spread, including those with RAS/BRAF wild-type disease who may face limited options after standard chemotherapy and targeted therapy,” said Ruth Vera, M.D., Medical Oncology Department, Hospital Universitario de Navarra, and study investigator. “The encouraging response rates observed in both the first- and second-line settings, along with the maturation of the dataset over time, suggest that treatment with petosemtamab plus chemotherapy may offer a potential new approach for these patients.”

As of May 15, 2026, 79 patients were treated with the petosemtamab combination, including 45 patients in the 1L setting and 34 patients in the 2L setting. Among efficacy-evaluable patients, confirmed and unconfirmed ORR was 75% in 1L patients and 67% in 2L patients. In 1L patients with left-sided tumors, ORR was 81%. Responses were observed across key patient subgroups, including patients with liver metastases, which is a poor prognostic factor in mCRC, with ORRs of 76% and 67% in the 1L and 2L settings, respectively. Median follow-up was 5.9 months in the 1L setting and 7.1 months in the 2L setting, with 76% and 74% of patients, respectively, remaining on treatment at the data cutoff. Disease control rate was 95% in 1L patients and 93% in 2L patients.

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Petosemtamab-related treatment-emergent adverse events (TEAEs) led to petosemtamab discontinuation in 2 of 42 patients (5%) treated with petosemtamab + mFOLFOX6 and in 1 of 37 patients (3%) treated with petosemtamab + FOLFIRI. No TEAEs leading to death were reported. Infusion-related reactions (IRRs) occurred in 48% of patients receiving petosemtamab plus FOLFOX and 43% of patients receiving petosemtamab plus FOLFIRI; grade 3 IRRs occurred in 3 of 42 (7%) and 1 of 37 (3%) patients, respectively.

“These updated Phase 2 results presented at ESMO continue to build on the encouraging clinical efficacy of petosemtamab,” said Tahamtan Ahmadi, M.D., Ph.D., Executive Vice President and Chief Medical Officer, Head of Experimental Medicines, Genmab. “The confirmation of previously unconfirmed responses with longer follow-up further reinforces the durability of responses observed across treatment lines and strengthens our confidence in petosemtamab. The data provide a compelling rationale for our ongoing global Phase 3 trials, where we aim to establish the potential benefit for patients in 1L and 2L settings.”

Petosemtamab has the only triple mechanism of action that uniquely targets the LGR5+ stem-like cancer cells that drive tumor recurrence and metastases in epithelial cancers. In addition to this ongoing Phase 1/2 trial ([NCT03526835](#)), the petosemtamab clinical program includes four Phase 3 LiGeR trials: in 1L PD-L1+ recurrent or metastatic head and neck squamous cell carcinoma (r/m HNSCC) (LiGeR-HN1; [NCT06525220](#)); in 2L/3L r/m HNSCC (LiGeR-HN2; [NCT06496178](#)), in 1L RAS/BRAF wild-type, left-sided unresectable or metastatic CRC (LiGeR-CRC1; [NCT07702032](#)); and in 2L RAS/BRAF wild-type recurrent, unresectable, or metastatic CRC (LiGeR-CRC2; [NCT07775287](#)).

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 Phase 2 Petosemtamab Trial (NCT03526835)

The Phase 2 trial ([NCT03526835](#)) is an ongoing, single-arm, open-label, multicenter study evaluating petosemtamab as monotherapy and in combination with standard-of-care therapies across multiple solid tumors, including metastatic colorectal cancer. Patients with left- and/or right-sided, RAS/BRAF wildtype, anti-EGFR naïve mCRC received 1500 mg of petosemtamab every two weeks plus FOLFOX or FOLFIRI until disease progression or unacceptable toxicity. Patients were treated either in 1L or 2L setting after one prior chemotherapy regimen. The primary endpoints include investigator-assessed objective response rate (ORR) and safety.

About Colorectal Cancer (CRC)

Colorectal cancer (CRC) is a malignant disease of the colon or rectum and is the third most commonly diagnosed cancer globally, with an estimated 1.9 million new cases annually.ⁱ While CRC is typically diagnosed in older adults, incidence is increasing among younger individuals in many countries.ⁱⁱ In metastatic CRC, treatment selection is increasingly informed by molecular characteristics, including RAS and BRAF mutation status, primary tumor sidedness, and prior therapy.ⁱⁱⁱ Patients with RAS/BRAF wild-type metastatic CRC may be eligible for EGFR-targeted

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treatment approaches in 1L settings for left-sided tumors and in 2L settings for both left- and right-sided tumors.ⁱⁱⁱ Survival outcomes vary widely by stage and geographic region, with an estimated five-year survival rate of 15% in late-stage metastatic CRC.^{iv}

About Petosemtamab (GEN1158)

Petosemtamab is an investigational human IgG1-based bispecific antibody targeting the EGFR and the LGR5 and designed to support multiple anti-tumor mechanisms. It inhibits EGFR-mediated signaling by engaging a unique site on the receptor to prevent ligand binding. In addition, petosemtamab triggers EGFR degradation in cancer stem-like cells expressing both EGFR and LGR5. Petosemtamab is also engineered to enhance innate immune-mediated activity through interactions with macrophages and natural killer cells. It is currently being investigated in head and neck squamous cell carcinoma (HNSCC) and other solid tumors, including colorectal cancer (CRC). 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, antibody drug conjugates (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) or follow us on [LinkedIn](#), [X](#), [Facebook](#) and [Instagram](#).

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ⁱ World Health Organization. "Colorectal cancer." *World Health Organization*, accessed May 14, 2026. <https://www.who.int/news-room/fact-sheets/detail/colorectal-cancer>.

ⁱⁱ Sung H, Siegel RL, Laversanne M, Jiang C, Morgan E, Zahwe M, Cao Y, Bray F, Jemal A. "Colorectal cancer incidence trends in younger versus older adults: an analysis of population-based cancer registry data." *Lancet Oncol*, 2025 Jan;26(1):51-63. doi: 10.1016/S1470-2045(24)00600-4. Epub 2024 Dec 12. PMID: 39674189; PMCID: PMC11695264.

ⁱⁱⁱ Cremolini C, Chalabi M, Elez E, et al. Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. *Annals of Oncology*. 2026.

^{iv} National Cancer Institute. "Colorectal cancer—cancer stat facts." Surveillance, Epidemiology, and End Results Program (SEER)", accessed May 14, 2026. [Cancer of the Colon and Rectum - Cancer Stat Facts](https://seer.cancer.gov/statfacts/html/colorec.htm)