

Genmab Announces Topline Results for Epcoritamab (DuoBody® CD3xCD20) from Phase 3 EPCORE® DLBCL-1 Trial in Patients with Relapsed/Refractory Diffuse Large B-cell Lymphoma (DLBCL)

Company Announcement

- Based on the topline results from the EPCORE® DLBCL-1 trial, Genmab will engage global regulatory authorities to discuss next steps

COPENHAGEN, Denmark; January 16, 2026 – Genmab A/S (Nasdaq: GMAB) today announced topline results from the Phase 3 EPCORE DLBCL-1 trial evaluating epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, which demonstrated an improvement in progression-free survival (PFS) (HR: 0.74 [95% CI 0.60 to 0.92])* in patients treated with epcoritamab monotherapy. Additionally, improvements were observed in the complete response rate, duration of response, and time to next treatment among patients treated with epcoritamab monotherapy. EPCORE DLBCL-1 is the first Phase 3 study to demonstrate an improvement in PFS in patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who were treated with a CD3xCD20 T-cell engaging bispecific monotherapy. The study demonstrated an overall survival (OS) of HR: 0.96 [95% CI 0.77 to 1.20], which did not reach statistical significance.

The global study enrolled 483 patients with R/R DLBCL with at least one prior line of therapy (73% had received two or more prior lines) who were ineligible for high-dose chemotherapy and autologous stem cell transplant (HDT-ASCT). The study evaluated the safety and efficacy of epcoritamab monotherapy compared to investigator's choice of either rituximab plus gemcitabine and oxaliplatin (R-GemOx), or bendamustine plus rituximab (BR).

The adverse events observed in this study appear consistent with the known safety profile of epcoritamab. Further analysis of the results is ongoing, including the potential impact of various factors, such as the COVID-19 pandemic and increasing availability of novel anti-lymphoma therapies. The full trial results will be submitted for presentation at a future medical meeting. Genmab and AbbVie will engage with global regulatory authorities to discuss next steps.

Data is anticipated in 2026 from two Phase 3 trials evaluating fixed duration epcoritamab in patients with DLBCL, including EPCORE DLBCL-2, a front-line study evaluating epcoritamab in combination with standard-of-care rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (R-CHOP), and EPCORE DLBCL-4, evaluating epcoritamab in combination with lenalidomide versus chemo-immunotherapy in patients with relapsed or refractory DLBCL.

"The EPCORE DLBCL-1 trial is the first Phase 3 study evaluating a bispecific antibody monotherapy to demonstrate improvements in progression-free survival in patients with relapsed or refractory DLBCL," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "The results from this global trial contribute to the growing body of evidence supporting epcoritamab and build upon the robust foundation established by epcoritamab, which has been used to treat thousands of patients in need of additional therapeutic options. Together with our partner, AbbVie, we remain deeply committed to advancing the development of epcoritamab as a potential core therapy across a broad range of B-cell malignancies."

Epcoritamab (approved under the brand name EPKINLY® in countries including the U.S. and Japan, and as TEPKINLY® in the European Union) has received regulatory approval in certain lymphoma indications in more than 65 countries. Genmab and AbbVie remain committed to advancing the potential of epcoritamab, with ongoing clinical programs evaluating the therapy as a monotherapy and in combination regimens across treatment lines and a broad range of hematologic malignancies.

*Based on intent-to-treat principle.

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About Diffuse Large B-Cell Lymphoma

Diffuse large B-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma (NHL) worldwide, accounting for approximately 25-30 percent of all NHL cases.^{i,ii} In the U.S., there are approximately 25,000 new cases of DLBCL diagnosed each year.ⁱⁱⁱ DLBCL can arise in lymph nodes as well as in organs outside of the lymphatic system, occurs more commonly in the elderly and is slightly more prevalent in men.^{iv,v} DLBCL is a fast-growing type of NHL, a cancer that develops in the lymphatic system and affects B-cell lymphocytes, a type of white blood cell. For many people living with DLBCL, their cancer either relapses, which means it may return after treatment, or becomes refractory, meaning it does not respond to treatment. Although new therapies have become available, treatment management can remain a challenge.^{iv,vi}

About the EPCORE DLBCL-1 Trial

EPCORE DLBCL-1 ([NCT04628494](https://www.clinicaltrials.gov/ct2/show/NCT04628494)) is a global Phase 3 open label, multi-center, randomized trial to evaluate the efficacy of epcoritamab (GEN3013, DuoBody®-CD3xCD20) compared to investigator's choice of chemotherapy, either rituximab plus gemcitabine plus and oxaliplatin (R-GemOx), or bendamustine plus rituximab (BR), in patients with relapsed or refractory DLBCL who are ineligible for high-dose chemotherapy and autologous stem cell transplant (HDT-ASCT). The trial started on January 13, 2021, and is ongoing.

More information on this trial can be found at <https://www.clinicaltrials.gov/>.

About Epcoritamab

Epcoritamab is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody technology and administered subcutaneously. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response toward target cell types. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T-cell-mediated killing of CD20+ cells.^{vii}

Epcoritamab (approved under the brand name EPKINLY® in the U.S. and Japan, and TEPKINLY® in the EU) has received regulatory approval in certain lymphoma indications in several territories. Where approved, epcoritamab is a readily accessible therapy. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. The companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Both companies will pursue additional international regulatory approvals for the investigational R/R FL indication and additional approvals for the R/R DLBCL indication.

Genmab and AbbVie continue to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes three ongoing Phase 3, open-label, randomized trials, among them a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL ([NCT05578976](https://www.clinicaltrials.gov/ct2/show/NCT05578976)), a trial evaluating epcoritamab in combination with lenalidomide compared to chemotherapy infusion in patients with R/R DLBCL ([NCT06508658](https://www.clinicaltrials.gov/ct2/show/NCT06508658)), and a trial evaluating epcoritamab in combination with lenalidomide and rituximab (R²) compared to chemoimmunotherapy in patients with previously untreated FL ([NCT06191744](https://www.clinicaltrials.gov/ct2/show/NCT06191744)). The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit www.clinicaltrials.gov for more information.

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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 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 Lymphoma Research Foundation. Diffuse Large B-Cell Lymphoma. Accessed December 2025. <https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/dlbcl/>

ⁱⁱ Padala, et al. Diffuse Large B-Cell Lymphoma. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. 2023 Apr 24.

ⁱⁱⁱ Leukemia and Lymphoma Society. Diffuse Large B-Cell Lymphoma (DLBCL). Accessed November 2024. <https://www.lls.org/research/diffuse-large-b-cell-lymphoma-dlbcl>

^{iv} Sehn, et al. Diffuse Large B-Cell Lymphoma. *N Engl J Med.* 2021;384:842-858. doi: 10.1056/NEJMra2027612.

^v Kanas, et al. Epidemiology of Diffuse Large B-Cell Lymphoma (DLBCL) and Follicular Lymphoma (FL) in the United States and Western Europe: Population-Level Projections for 2020-2025. *Leuk Lymphoma.* 2022;63(1):54-63. doi: 10.1080/10428194.2021.1975188.

^{vi} Crump, et al. Outcomes in Refractory Diffuse Large B-Cell Lymphoma: Results From the International SCHOLAR-1 Study. *Blood.* 2017;130(16):1800-1808. doi: 10.1182/blood-2017-03-769620.

^{vii} Engelberts PJ, Hiemstra IH, de Jong B, et al. DuoBody-CD3xCD20 induces potent T-cell-mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing. *EBioMedicine.* 2020;52:102625. DOI: 10.1016/j.ebiom.2019.102625.