

Genmab and AbbVie Announce Epcoritamab in Combination with R-CHOP Demonstrates Statistically Significant Improvement in Progression-Free Survival in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma

Company Announcement

COPENHAGEN, Denmark and NORTH CHICAGO, Ill.; October 5, 2026

- **EPCORE DLBCL-2 is the first Phase 3 study of a bispecific antibody combination therapy to demonstrate statistically significant and clinically meaningful improvement in progression-free survival (PFS) in frontline diagnosed diffuse large B-cell lymphoma (DLBCL) patients**
- **Based on the topline results, Genmab and AbbVie will engage global regulatory authorities**

Genmab A/S (Nasdaq: **GMA**) and **AbbVie** (NYSE: **ABBV**) announced today positive topline results from the Phase 3 EPCORE DLBCL-2 trial evaluating fixed treatment duration epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, in combination with standard of care rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (R-CHOP), compared to R-CHOP alone, in newly diagnosed patients with diffuse large B-cell lymphoma (DLBCL) with an International Prognostic Index (IPI) score of 2 to 5. The trial demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) in DLBCL patients with an IPI score of 2 to 5. The risk of disease progression or death was reduced by 51% (HR 0.49 [95% CI 0.36, 0.67]; p-value < 0.0001). The safety profile of epcoritamab when administered in combination with standard of care R-CHOP was generally well tolerated and consistent with the previously reported safety profiles of the individual agents (epcoritamab and R-CHOP).

"These topline results of epcoritamab in combination with R-CHOP mark the first Phase 3 study to demonstrate a statistically significant improvement in progression-free survival in patients with newly diagnosed DLBCL treated with a bispecific antibody combination and have the potential to reshape the frontline treatment landscape," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "While treatment advances have improved outcomes for patients with diffuse large B-cell lymphoma, options for newly diagnosed patients remain limited, reinforcing the need for additional therapies that can treat as many patients as possible in the frontline setting."

"DLBCL is an aggressive disease and the need to advance treatment options is critical. These positive topline results suggest that epcoritamab combined with R-CHOP could offer a potential new standard of care in newly diagnosed DLBCL patients," said Daejin Abidoye, MD, vice president, therapeutic area head, oncology, solid tumor and hematology, AbbVie. "The findings further strengthen our understanding and potential of bispecifics across the lymphoma treatment landscape, as we work to address urgent needs in this patient population."

"As an investigator with firsthand experience in both the landmark trial that established R-CHOP as a standard of care nearly 25 years ago and EPCORE DLBCL-2, it is particularly meaningful to see the potential benefit of bispecific antibody therapy in newly diagnosed diffuse large B-cell lymphoma," said Gilles Salles, MD, PhD, Chief of the Lymphoma Service and holder of the Steven A. Greenberg Chair at Memorial Sloan Kettering Cancer Center. "The 51% reduction in the risk of progression or death is clinically meaningful and highly relevant to everyday practice. These results have the potential to be practice-changing and could mark an important step forward in bringing the opportunity of cure to more patients."

Data will be submitted for presentation at a future medical meeting. Genmab and AbbVie will engage global regulatory authorities to determine next steps. Epcoritamab plus R-CHOP is an investigational combination not approved by regulatory authorities.

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About the EPCORE[®] DLBCL-2 Trial

EPCORE DLBCL-2 ([NCT05578976](https://clinicaltrials.gov/study/NCT05578976)) is a global Phase 3 open label, multi-center, randomized trial to evaluate the efficacy of fixed duration, subcutaneous epcoritamab (GEN3013, DuoBody[®]-CD3xCD20) and standard of care rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (R-CHOP) compared to R-CHOP alone in patients with newly diagnosed large B-cell lymphoma (DLBCL). The trial enrolled subjects with an International Prognostic Index (IPI) score of 2 to 5, including patients with diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), high-grade B-Cell lymphoma (HGBL) with MYC and BCL2 and/or BCL6 rearrangements, follicular lymphoma grade 3B (FL3B), T-cell/histiocyte-rich large B-Cell lymphoma (TCHR LBCL), and Epstein-Barr Virus-positive diffuse large B-cell lymphoma (EBV+ DLBCL). The primary endpoint is PFS in participants with an International Prognostic Index (IPI) of 3-5 and the key secondary endpoint is PFS in total participants (IPI score of 2-5). The risk of disease progression or death for the primary endpoint population was reduced by 51% (HR 0.49 [95% CI 0.35, 0.69]; p-value < 0.0001). Patients were randomized 2:1 to receive a fixed-duration regimen of epcoritamab plus R-CHOP for six cycles followed by epcoritamab alone for two cycles, or R-CHOP for six cycles followed by rituximab for two cycles. The trial started on February 8, 2023, and is ongoing.

More information on this trial can be found at <https://clinicaltrials.gov/study/NCT05578976> (NCT: NCT05578976).

About Diffuse Large B-Cell Lymphoma

Diffuse large B-cell lymphoma (DLBCL) 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 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 more than 65 countries. 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 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 relapsed or refractory (R/R) follicular lymphoma (FL) indication and additional approvals for the R/R diffuse large B-cell lymphoma (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 a trial evaluating

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epcoritamab in combination with lenalidomide and rituximab (R²) compared to chemoimmunotherapy in patients with previously untreated FL ([NCT06191744](#)). The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit www.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 or follow us on [LinkedIn](#), [X](#), [Facebook](#) and [Instagram](#).

About AbbVie in Oncology

AbbVie is committed to elevating standards of care and bringing transformative therapies to patients worldwide living with difficult-to-treat cancers. We are advancing a dynamic pipeline of investigational therapies across a range of cancer types in both blood cancers and solid tumors. We are focusing on creating targeted medicines that either impede the reproduction of cancer cells or enable their elimination. We achieve this through various, targeted treatment modalities and biology interventions, including small molecule therapeutics, antibody-drug conjugates (ADCs), immuno-oncology-based therapeutics, multispecific antibody and novel CAR-T platforms. Our dedicated and experienced team joins forces with innovative partners to accelerate the delivery of potential breakthrough medicines.

Today, our expansive oncology portfolio is comprised of approved and investigational treatments for a wide range of blood and solid tumors. We are evaluating more than 35 investigational medicines across some of the world's most widespread and debilitating cancers. As we work to have a remarkable impact on people's lives, we are committed to exploring solutions to help patients obtain access to our cancer medicines. For more information, please visit us at <http://www.abbvie.com/oncology>.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas including immunology, neuroscience and oncology – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on [LinkedIn](#), [Facebook](#), [Instagram](#), [X](#) and [YouTube](#).

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Genmab Forward-Looking Statements

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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AbbVie Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions and uses of future or conditional verbs, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry, the impact of global macroeconomic factors, such as economic downturns or uncertainty, international conflict, trade disputes and tariffs, and other uncertainties and risks associated with global business operations. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2025 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its Quarterly Reports on Form 10-Q and in other documents that AbbVie subsequently files with the Securities and Exchange Commission that update, supplement or supersede such information. AbbVie undertakes no obligation, and specifically declines, to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

ⁱ Lymphoma Research Foundation. Diffuse Large B-Cell Lymphoma. Accessed February 2026. <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 February 2026. <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.