# Genmab Announces Epcoritamab Monotherapy and Epcoritamab-Based Combination Regimens Demonstrate High Response Rates in Elderly Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

## Media Release

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- **Results from the Phase 2 EPCORE® DLBCL-3 trial show fixed-duration epcoritamab monotherapy demonstrated early responses in elderly patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL) ineligible for anthracycline-based chemotherapy**
- **Results from the Phase 1b/2 EPCORE® NHL-2 trial show fixed-duration epcoritamab plus standard of care R-mini-CHOP demonstrated sustained minimal residual disease (MRD) negativity and durable remissions in elderly patients with newly diagnosed DLBCL ineligible for full dose R-CHOP**
- **Data were presented at the 2026 European Hematology Association (EHA) Congress**

**Genmab A/S (Nasdaq: GMAB) today announced new data from two studies evaluating epcoritamab, a T-cell engaging antibody administered subcutaneously, in the first-line (1L) treatment of patients with diffuse large B-cell lymphoma (DLBCL) who may have limited treatment options due to advanced age or multiple health conditions.** Results from the Phase 2 EPCORE® DLBCL-3 study showed an overall response rate (ORR) of 67% and a complete response (CR) rate of 58% with epcoritamab monotherapy in elderly patients with newly diagnosed DLBCL. In the Phase 1b/2 EPCORE NHL-2 study, epcoritamab plus rituximab plus dose-attenuated cyclophosphamide, doxorubicin, vincristine, and prednisone (R-mini-CHOP) demonstrated an ORR of 93% and a CR rate of 86% in elderly patients with newly diagnosed DLBCL.

The results from both studies were presented in two poster presentations (abstracts PS2082 and PF1007) at the European Hematology Association (EHA) 2026 Congress held in Stockholm, Sweden, June 11-14. Additionally, the full EPCORE DLBCL-3 results have been simultaneously published in *The Lancet Haematology*.

**EPCORE DLBCL-3 Results**

The Phase 2 EPCORE DLBCL-3 study (abstract PS2082) evaluated the efficacy and safety of fixed-duration epcoritamab monotherapy in newly diagnosed CD20+ large B-cell lymphoma (LBCL) patients ineligible for anthracycline-based chemotherapy due to age (≥80 years) or comorbidities (≥75 years with comorbidities). Among 66 enrolled patients, the median age was 82.5 years, and all had comorbid conditions (94% with ≥3 comorbidities). With a median follow-up of 21.9 months, epcoritamab monotherapy demonstrated responses in this population with high unmet medical need.

An ORR of 67% and a CR rate of 58% were observed in evaluable patients (n=66). Median time to response was 1.5 months, and median time to CR was 2.2 months. Notably, 11 of 17 patients with a partial response or stable disease at first assessment subsequently achieved a CR.

"For newly diagnosed elderly patients with diffuse large B-cell lymphoma and comorbidities, who are often excluded from standard curative chemotherapy and ineligible for doxorubicin, finding more options is paramount," said Umberto Vitolo, M.D. Candiolo Cancer Institute, FPO-IRCCS, Candiolo (Turin), Italy. "The EPCORE DLBCL-3 study showed that epcoritamab monotherapy offers robust data. Importantly, its safety profile, including cytokine release syndrome and immune effector cell–associated neurotoxicity syndrome, was consistent with expected rates in this fragile population with a high unmet medical need for new therapeutic options."

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Responses were durable, with median duration of response (DOR) and duration of complete response (DOCR) not reached. At 12 months, an estimated 67% of responses and 73% of CRs remained ongoing. Median progression-free survival (PFS) was 13.0 months, while median overall survival (OS) was not reached; an estimated 43% of patients remained progression-free and 62% were alive at 18 months. High rates of minimal residual disease (MRD) negativity were observed, with 92% of evaluable responders achieving MRD negativity, typically by Cycle 3 Day 1 and sustained through Cycle 12 Day 1 in most patients.

The safety profile was consistent with expected rates in this elderly population. Cytokine release syndrome (CRS) occurred in 71% of patients, most commonly during Cycle 1, and immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in 18%. Infections of any grade occurred in 68% of patients (26% Grade ≥3), and neutropenia was reported in 16%, with no febrile neutropenia or clinical tumor lysis syndrome observed. Eight Grade 5 TEAEs occurred.

**EPCORE NHL-2, Arm 8 Results**

Arm 8 of the Phase 1b/2 EPCORE NHL-2 study (abstract PF1007) evaluated epcoritamab plus R-mini-CHOP in 28 newly diagnosed CD20+ DLBCL patients ineligible for full-dose R-CHOP due to age (≥75 years) or comorbidities (≥65 years with comorbidities). With more than two years of follow-up, fixed-duration epcoritamab plus R-mini-CHOP demonstrated high response rates, sustained MRD negativity and durable remissions.

An ORR of 93% and a CR rate of 86% were observed. Median DOR, DOCR, PFS, and OS were not reached. At two years, estimated DOR and DOCR rates were 79%, while estimated PFS and OS rates were 76% and 82%, respectively.

“The EPCORE NHL-2 Arm 8 results are very encouraging, showing that combining epcoritamab with R-mini-CHOP led to high overall response rates and complete response rates, rapid and sustained minimal residual disease negativity, and durable remissions in this population,” said David Belada, M.D., Department of Internal Medicine—Haematology, Charles University, Hospital and Faculty of Medicine, Hradec Králové, Czech Republic. “These outcomes, alongside a consistent safety profile, potentially support the integration of epcoritamab with standard of care for these vulnerable patients, and highlight its broad utility in combinations across a range of disease settings and patient populations."

Rapid and sustained MRD negativity was observed, with 95% of evaluable patients achieving MRD negativity, including high rates in high-risk subgroups. Outcomes compared favorably with historical results for R-mini-CHOP alone.

The safety profile was consistent with prior reports and the known safety profiles of epcoritamab and R-mini-CHOP. The most common Grade ≥3 treatment-emergent adverse events (TEAEs) were neutropenia (54%), serious infections (33%) and anemia (14%). Most Grade ≥3 serious infections occurred during the first six cycles of treatment with R-mini-CHOP coadministration. TEAEs led to epcoritamab discontinuation in three patients (11%).

“Genmab is committed to evaluating epcoritamab as a potential treatment option in earlier lines of therapy for patients who traditionally struggle with aggressive treatment," said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. "The robust data observed in both the monotherapy and combination approaches reinforce our vision of making epcoritamab a foundational therapy across the spectrum of B-cell malignancies. These Phase 2 results support our ongoing commitment to addressing the significant unmet medical needs of elderly and comorbid patients, as we seek to identify effective, less intensive and tolerable options."

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**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] 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.[iii,iv] 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,v]

**About the EPCORE® DLBCL-3 Trial**
EPCORE DLBCL-3 (NCT05660967) is an open-label, randomized, global, Phase 2 trial to evaluate the efficacy and safety of epcoritamab as monotherapy or in combination with lenalidomide as first-line therapy for anthracycline-ineligible subjects with diffuse large B-cell lymphoma (DLBCL). This is a 2-stage trial. In Stage 1, eligible patients were randomized to either epcoritamab monotherapy or epcoritamab plus lenalidomide. In Stage 2, additional patients were enrolled to the epcoritamab monotherapy arm. Each treatment cycle is 28 days. Patients will receive a maximum of 12 cycles (up to 1 year) of treatment. The primary objective is to evaluate the clinical efficacy of epcoritamab monotherapy or epcoritamab and lenalidomide. The primary endpoint is to achieve a complete response rate determined by Lugano criteria. Additional secondary endpoints include overall response rate, duration of response, duration of complete response, rate of minimal residual disease negativity, progression-free survival and overall survival.

More information on this trial can be found at www.clinicaltrials.gov/.

**About the EPCORE® NHL-2 Trial**
EPCORE NHL-2 (NCT04663347) is a Phase 1b/2 open-label interventional trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics/biomarkers, immunogenicity, and preliminary efficacy of epcoritamab as a monotherapy and in combination with other standard of care agents in patients with B-cell non-Hodgkin lymphoma (B-NHL). The trial consists of two parts: Part 1 (Dose Escalation) and Part 2 (Dose Expansion). The primary objective of Part 1 is safety, and the primary goal of Part 2 is preliminary efficacy. The primary efficacy endpoint is overall response rate (ORR) based on best overall response per Lugano criteria. MRD negativity was assessed as a secondary endpoint.

More information on this trial can be found at 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.[vi]

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 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 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 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 several Phase 3, open-label, randomized trials, including a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL (NCT05578976), a trial evaluating epcoritamab in combination with lenalidomide compared to chemotherapy infusion in patients with R/R DLBCL (NCT06508658), and a trial evaluating epcoritamab in combination with lenalidomide and rituximab ($R^2$) 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 and follow us on LinkedIn and X.

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