Genmab Announces Updated Results from Phase 2 EPCORE® NHL-6 Study Evaluating Epcoritamab Monotherapy in the Outpatient Setting in Patients with Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL)

Media Release

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- **Trial demonstrated the feasibility of treating and monitoring adult patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) in an outpatient setting**
- **Results showed that 92% of patients with R/R DLBCL received the first full dose of epcoritamab monotherapy in an outpatient setting**
- **Adverse event profile and efficacy were consistent with previously reported studies in R/R DLBCL patients**
- **Data also demonstrated 64.3% overall response rate with a complete response rate of 47.6% in patients treated with epcoritamab following one prior line of systemic DLBCL therapy**

Genmab A/S (Nasdaq: GMAB) today announced updated results from the Phase 2 EPCORE® NHL-6 trial (NCT05451810) evaluating the safety and efficacy of investigational epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, as a monotherapy administered in the outpatient setting in adult patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who have received at least one prior line of systemic therapy, including at least one anti-CD20 monoclonal antibody-containing therapy. The study demonstrated the feasibility of treating and monitoring patients in an outpatient setting following the first dose of epcoritamab and showed that the incidence and severity of adverse events associated with epcoritamab were consistent with previous epcoritamab studies in patients with R/R DLBCL. These results were shared today during a poster presentation (Abstract #ABCL-1224) at the 13th Society of Hematologic Oncology (SOHO) Annual Meeting.

In the study, 88 patients received the first full dose (48 mg) of epcoritamab monotherapy. Of these, 81 patients (92%) received the first full dose in the outpatient setting and seven (8%) in the inpatient setting. Among the 81 treated and monitored as outpatients, 57 (70%) did not experience cytokine release syndrome (CRS) during the first full dose period. CRS occurred with the first full dose in 24 (30%) patients (21 patients in the outpatient setting; three patients in the inpatient setting, admitted for reasons unrelated to CRS), all Grade 1–2 events, with 10 (12%) patients managed in the outpatient setting, and 11 (13.6%) requiring inpatient care. Overall, CRS events occurred in 37 (40.2%) patients in the entire trial period, were primarily low grade (Grade 1-2), all resolved with a median time of two days, and no events led to treatment discontinuation. Immune cell-associated neurotoxicity syndrome (ICANS) occurred in seven patients (7.6%), were primarily low grade (Grade 1-2), all resolved with a median time of three days, and no events led to treatment discontinuation.

“The EPCORE NHL-6 trial results are notable, as current bispecific antibody treatments for relapsed and refractory diffuse large B-cell lymphoma patients may require in-hospital monitoring for cytokine release syndrome after certain initial doses and as needed after subsequent doses,” said Jeff Sharman, M.D., Disease Chair, Hematology Research, Sarah Cannon

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Research Institute (SCRI) at Willamette Valley Cancer Institute in Eugene, Oregon. “The possibility of treating patients in the outpatient setting is encouraging and it may enable more people to have access to this treatment option across various sites of care, including community settings.”

The study also demonstrated an overall response rate (ORR) of 64.3% and a complete response (CR) rate of 47.6%, at a median follow up of 5.8 months in patients (n=42) treated with epcoritamab after only one prior line of systemic therapy. In patients treated with epcoritamab following two or more lines of systemic therapy (n=50), with a median follow up of 10.8 months, the study showed an ORR of 60.0% and a CR rate of 38.0%.

“Together with our partner AbbVie, we remain committed to advancing research that supports people living blood cancer no matter where they are in their treatment journey and developing epcoritamab as a potential core therapy across B-cell malignancies,” said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer at Genmab.

The safety and efficacy of investigational epcoritamab for use in the outpatient setting for first full dose in R/R DLBCL in the second-line setting has not been approved by US FDA or any other Health Authority.

About 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. In the U.S., there are approximately 25,000 new cases of DLBCL diagnosed each year. 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. 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 become refractory, meaning it does not respond to treatment. Although new therapies have become available, treatment management can remain a challenge.

About the EPCORE® NHL-6 Trial
EPCORE NHL-6 is a Phase 2 open-label clinical trial evaluating the safety of outpatient administration of subcutaneous epcoritamab monotherapy in adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL). The primary objective of the trial was to assess adverse events within three months of treatment initiation with epcoritamab monotherapy. The primary outcome measures were percentage of participants experiencing Grade 3 or higher cytokine release syndrome (CRS) events, immune cell-associated neurotoxicity syndrome (ICANS) events and/or neurotoxicity (Ntox) events. Secondary outcomes included responses to treatment. The study was conducted across community and academic sites in the U.S.

EPCORE NHL-6 enrolled 92 patients with R/R DLBCL who had received at least one prior line of systemic therapy, including at least one anti-CD20 monoclonal antibody-containing therapy. At the time of data cutoff (January 15, 2025), 92 patients had received one or more dose of

epcoritamab, the median follow-up was 7.6 months (range, 6.0-9.2), and half of patients remained on treatment. Median age was 69 years, 82.6 percent had Ann Arbor stage III-IV. 24 percent had prior CAR T, 24 percent had bulky disease ≥7cm, and 51 percent had International Prognostic Index (IPI) ≥3. Of note 42 of patients had 1 prior line of therapy. More information can be found at https://www.clinicaltrials.gov/ (NCT05451810).

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.[i]

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. 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 investigational R/R follicular lymphoma (FL) uses and additional approvals for R/R DLBCL investigational uses.

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 five ongoing Phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL compared to investigators choice chemotherapy (NCT04628494), a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL (NCT05578976), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R2) in patients with R/R FL (NCT05409066), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R2) compared to chemoimmunotherapy in patients with previously untreated FL (NCT06191744), and a trial evaluating epcoritamab in combination with R2 compared to chemotherapy in patients with R/R DLBCL (NCT06508658). 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 with a core purpose of guiding its unstoppable team to strive toward improving the lives of patients with innovative and differentiated antibody therapeutics. For 25 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational, quantitative and data sciences, resulting in a proprietary pipeline including bispecific T-cell engagers, antibody-drug conjugates, next-generation immune checkpoint modulators and effector function-enhanced antibodies. By 2030, Genmab's vision is to transform the lives of people with cancer and other serious diseases with knock-your-socks-off (KYSO) antibody medicines®.

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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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[i] Engelberts PJ, 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.