

## Genmab Announces Epcoritamab Investigational Combination Therapy Demonstrates High Response Rates in Patients with Relapsed or Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) Eligible for Autologous Stem Cell Transplantation (ASCT)

### Media Release

COPENHAGEN, Denmark; June 15, 2025

- Results from the EPCORE<sup>®</sup> NHL-2 trial show investigational treatment with epcoritamab in combination with rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) led to an overall response rate (ORR) of 87 percent and a complete response (CR) rate of 65 percent in patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)
- Data further demonstrates the potential of epcoritamab in combination with salvage chemoimmunotherapy to increase the proportion of patients to qualify for Autologous Stem Cell Transplantation (ASCT)
- Data was presented during an oral session at the 30<sup>th</sup> European Hematology Association (EHA) Congress

**Genmab A/S** (Nasdaq: **GMAB**) today announced new results from the Phase 1b/2 EPCORE<sup>®</sup> NHL-2 trial Arm 10 ([NCT04663347](#)), evaluating epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, in combination with rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) in adult patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) who are eligible for autologous stem cell transplantation (ASCT). Results demonstrated an overall response rate (ORR) of 87 percent, a complete response (CR) rate of 65 percent and a partial response (PR) of 23 percent. The majority of patients (65 percent) proceeded to ASCT. At six months, an estimated 81 percent of responses were ongoing, 74 percent of patients were progression free, and 100 percent of patients were alive. These results were shared today during an oral presentation at the 30<sup>th</sup> European Hematology Association (EHA) 2025 Congress.

The safety profile of this combination therapy showed cytokine release syndrome (CRS) being low grade and no discontinuations due to treatment-emergent adverse events (TEAEs). The most common TEAEs were neutropenia (74 percent), anemia (68 percent), and thrombocytopenia (68 percent). CRS occurred in 52 percent; all were low grade (1/2) and resolved. One patient had immune effector cell-associated neurotoxicity syndrome (ICANS; grade 1), which resolved. No clinical tumor lysis syndrome was observed. Infections occurred in 18 patients (58 percent); five (16 percent) had serious infections. There were no Grade 5 TEAEs.

“These results are particularly encouraging because many of the patients in this study had high-risk disease, having progressed rapidly after initial treatment,” said Raul Cordoba, MD, PhD, Head of the Lymphoma Unit at the Fundacion Jimenez Diaz University Hospital, Madrid, Spain. “This combination therapy of epcoritamab plus rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) offers a potential new treatment option for patients with relapsed/refractory diffuse large B-cell lymphoma, providing high response rates and a bridge to potentially curative autologous stem cell transplantation.”

Among patients in the study who progressed within 12 months after first-line treatment (n=20), epcoritamab in combination with R-ICE demonstrated an 85 percent ORR and 55 percent CR. Patients in the study who progressed after 12 months from first-line therapy experienced a 91 percent ORR and 82 percent CR. Additionally, patients with one prior line of therapy experienced an 88 percent ORR and 68 percent CR, and patients who were treated with more than one prior line of therapy experienced an 83 percent ORR and 50 percent CR.

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"The results from this trial highlight the potential of this investigational epcoritamab containing regimen, especially in patients who progress quickly after initial treatment, and reinforce our joint efforts with AbbVie to develop epcoritamab as a core therapy for B-cell lymphomas, especially as we develop epcoritamab in earlier lines of therapy and a broader patient population," said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. "Our comprehensive EPCORE clinical trial program is dedicated to advancing epcoritamab as both monotherapy and in combination to address the significant unmet need in relapsed/refractory diffuse large B-cell lymphoma and other hematologic malignancies."

Use of epcoritamab + R-ICE in patients with R/R DLBCL eligible for ASCT is not approved and the safety and efficacy of epcoritamab for use as a combination therapy in DLBCL have not been established.

### **About Diffuse Large B-Cell Lymphoma**

DLBCL is the most common type of non-Hodgkin's 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 becomes refractory, meaning it does not respond to treatment. Although new therapies have become available, treatment management can remain a challenge.

### **About the EPCORE<sup>®</sup> NHL-2 Trial**

EPCORE NHL-2 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's 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 endpoint was overall response rate (ORR) based on best overall response per Lugano criteria. MRD negativity was assessed as a secondary endpoint.

Arm 10 of the EPCORE NHL-2 study enrolled 31 patients with R/R DLBCL, who were eligible for R-ICE and ASCT, and had received  $\geq 1$  prior line of treatment. At the time of data cutoff (December 18, 2024), median follow-up was 11 months (range, 6–15). Among the 31 patients treated with epcoritamab 48 mg + R-ICE, 61 percent were Ann Arbor stage III/IV, 42 percent had bulky disease  $\geq 7$  cm, 81 percent had one prior LOT (range, 1–3), and 65 percent had progressed within 12 months of first-line treatment. More information on this trial can be found at <https://www.clinicaltrials.gov/> (NCT: 04663347).

### **About Epcoritamab**

Epcoritamab is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody<sup>®</sup> 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.<sup>1</sup>

Epcoritamab (approved under the brand name EPKINLY<sup>®</sup> in the U.S. and Japan, and TEPKINLY<sup>®</sup> in the EU) has received regulatory approval in certain lymphoma indications in several territories. Where

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approved, epcoritamab is available as a readily accessible therapy without the need for reducing tumor burden (“debulking”). 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 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 infusion 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](http://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<sup>®</sup>) antibody medicines.

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](http://Genmab.com) and follow us on [LinkedIn](#) and [X](#).

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which are available at [www.sec.gov](http://www.sec.gov). Genmab does not undertake any obligation to update or revise forward looking statements in this Media Release 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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<sup>1</sup> 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.