Genmab Announces Phase 3 EPCORE® FL-1 Clinical Trial Met Dual Primary Endpoints in Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL)

Company Announcement

COPENHAGEN, Denmark; August 7, 2025

- **Epcoritamab in combination with rituximab and lenalidomide (R^2) demonstrated statistically significant improvement in Overall Response Rate (ORR; 95.7%, p < 0.0001) and Progression-Free Survival (HR 0.21, p-value <0.0001) versus R^2 alone in patients with relapsed/refractory (R/R) Follicular Lymphoma (FL)**
- **Results from EPCORE FL-1 form the basis of global regulatory submissions**
- **U.S. FDA has accepted for priority review new supplemental Biologics License Application (sBLA) for epcoritamab plus R^2, with action date of November 30, 2025**
- **If approved, epcoritamab plus R^2 would be the first bispecific antibody combination regimen available as a second-line treatment option for patients with R/R FL**

Genmab A/S (Nasdaq: GMAB) today announced positive results of the Phase 3 EPCORE® FL-1 trial evaluating subcutaneous epcoritamab, a bispecific antibody, in combination with rituximab and lenalidomide (R^2) versus R^2 alone for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL). The study met its dual primary endpoints of overall response rate (ORR, p-value < 0.0001) and progression-free survival (PFS, HR 0.21, p-value <0.0001), demonstrating statistically significant and clinically meaningful differences in both endpoints, reducing the risk of disease progression or death by 79%. The results, derived from a pre-planned interim analysis, will be submitted for presentation at the 67th Annual Meeting and Exposition of the American Society of Hematology (ASH) and will serve as the basis for global regulatory submissions.

Separately, on July 24, the U.S. Food and Drug Administration (FDA) accepted for priority review the supplemental Biologics License Application (sBLA) for epcoritamab plus R^2 following at least one prior systemic therapy. The sBLA submission was based on data from a first interim analysis that demonstrated statistically significant improvements in ORR (95.7%, p-value < 0.0001) and PFS (HR 0.21, p-value <0.0001, based on the intent-to-treat population). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of November 30, 2025. If approved, epcoritamab plus R^2 would be the first bispecific antibody combination regimen available in the U.S. as a second-line treatment option for patients with R/R FL.

“While therapeutic options exist for patients with relapsed or refractory follicular lymphoma, response rates tend to decline and durability diminishes with each subsequent line of treatment, which can increase the risk of the disease transforming into aggressive large-cell lymphoma,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “The results from this trial, and the decision from the FDA to accept the sBLA for priority review, demonstrate the potential of this epcoritamab combination therapy to reshape the treatment landscape and reinforces our shared commitment with AbbVie to advance epcoritamab as a potential core therapy across B-cell malignancies.”

The safety profile of epcoritamab in combination with R^2 in adult patients with R/R FL was consistent with the known safety profiles of the individual regimens (epcoritamab and R^2) and as presented in the U.S. prescribing information for epcoritamab. No new safety signals were observed. The U.S. FDA has granted accelerated approval of single agent epcoritamab for the treatment of adults with R/R FL after two or more lines of systemic therapy. The U.S. FDA also granted Breakthrough Therapy Designation (BTD) to epcoritamab in combination with R2 for the treatment of adult patients with R/R FL who have received at least one prior line of therapy. The safety and efficacy of epcoritamab in combination with R2 in R/R FL is currently being evaluated in clinical trials and is not approved or established in the U.S., EU or in any other territory.

Genmab Announces Phase 3 EPCORE® FL-1 Clinical Trial Met Dual Primary Endpoints in Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL)

About Follicular Lymphoma (FL)

FL is typically an indolent (or slow-growing) form of non-Hodgkin's lymphoma (NHL) that arises from B-lymphocytes and is the second most common form of NHL accounting for 20-30 percent of all cases.[i] About 15,000 people develop FL each year in the U.S.[ii] and it is considered incurable with current standard of care therapies.[iii] Patients often relapse and, with each relapse the remission and time to next treatment is shorter.[iv] Over time, transformation to diffuse large B-cell lymphoma (DLBCL), an aggressive form of NHL associated with poor survival outcomes, can occur in more than 25 percent of FL patients.[v]

About the EPCORE FL-1 Trial

EPCORE FL-1 (NCT05409066) is a Phase 3 open-label interventional trial to evaluate the safety and efficacy of epcoritamab plus rituximab and lenalidomide (R^2) versus R^2 alone in patients with relapsed/refractory (R/R) follicular lymphoma (FL). The dual primary endpoints are ORR and PFS assessed by independent review committee (IRC) per Lugano criteria.

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 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 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 (R^2) in patients with R/R FL (NCT05409066), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R^2) compared to chemoimmunotherapy in patients with previously untreated FL (NCT06191744), and a trial evaluating epcoritamab in combination with lenalidomide 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 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.

Genmab Announces Phase 3 EPCORE® FL-1 Clinical Trial Met Dual Primary Endpoints in Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL)

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.

Contact:
Marisol Peron, Senior Vice President, Global Communications & Corporate Affairs
T: +1 609 955 2392; E: mmp@genmab.com

Andrew Carlsen, Vice President, Head of Investor Relations
T: +45 3377 9558; E: acn@genmab.com

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.

---

[i] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed November 2024.
[ii] Leukemia & Lymphoma Society. https://www.lls.org/research/follicular-lymphoma-fl. Accessed November 2024.
[iii] Ghione P, Palomba ML, Ghesquieres H, et al. Treatment patterns and outcomes in relapsed/refractory follicular lymphoma: results from the international SCHOLAR-5 study. *Haematologica*. 2023;108(3):822-832. doi: 10.3324/haematol.2022.281421.
[iv] Rivas-Delgado A, Magnano L, Moreno-Velázquez M, et al. Response duration and survival shorten after each relapse in patients with follicular lymphoma treated in the rituximab era. *Br J Haematol*. 2018;184(5):753-759. doi:10.1111/bjh.15708.
[v] Al-Tourah AJ, Gill KK, Chhanabhai M, et al. Population-based analysis of incidence and outcome of transformed non-Hodgkin's lymphoma. *J Clin Oncol*. 2008 Nov 10;26(32):5165-9. doi: 10.1200/JCO.2008.16.0283. Epub 2008 Oct 6. PMID: 18838711.
[vi] 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.