# Genmab Presents Pivotal Phase 3 Data from EPCORE® FL-1 Trial Demonstrating Clinical Benefit of EPKINLY® (epcoritamab-bysp) in Combination with Rituximab and Lenalidomide ($R^2$) in Patients with Relapsed or Refractory Follicular Lymphoma

## Media Release

**COPENHAGEN, Denmark; December 7, 2025**

- **Trial demonstrated treatment with fixed duration EPKINLY plus rituximab and lenalidomide (EPKINLY+ $R^2$) resulted in statistically significant and clinically meaningful reduction in the risk of disease progression or death and overall response compared to $R^2$ alone**
- **EPKINLY + $R^2$ was recently approved by the U.S. Food and Drug Administration as the first and only bispecific-based therapy for follicular lymphoma in the second-line setting**
- **Results of EPCORE FL-1 simultaneously published in *The Lancet***

**Genmab A/S (Nasdaq: GMAB) today announced primary data from the pivotal Phase 3 EPCORE® FL-1 study evaluating fixed duration EPKINLY® (epcoritamab-bysp) in combination with rituximab and lenalidomide (EPKINLY + $R^2$) in adult patients with relapsed or refractory (R/R) follicular lymphoma (FL).** The study showed that treatment with EPKINLY + $R^2$ reduced the risk of disease progression or death by 79% (HR 0.21, 95% CI: 0.14-0.31, p<0.0001) compared to standard of care $R^2$. Additionally, the overall response rate (ORR) in patients treated with EPKINLY + $R^2$ was 95% (95% CI: 91.5, 97.4) compared to 79% in patients treated with $R^2$ (95% CI: 73.6, 84.1; P<.0001). The EPCORE FL-1 study results were presented during an oral presentation (abstract 466) at the 67th Annual Meeting and Exposition of the American Society of Hematology (ASH) in Orlando, Florida, featured in the "Emerging Therapies and Immunotherapies in Blood Cancers" ASH press briefing, and have been simultaneously published in *The Lancet*.

"Patients with relapsed or refractory follicular lymphoma have historically had limited treatment options," said Lorenzo Falchi, M.D., Lymphoma Specialist, Department of Medicine, Memorial Sloan Kettering Cancer Center. "The EPCORE FL-1 results demonstrate that epcoritamab plus $R^2$ is the first bispecific antibody-based, chemotherapy-free combination to show superior clinical benefit over standard of care in a Phase 3 trial, underscoring its potential to redefine the second-line treatment landscape for follicular lymphoma."

The EPCORE FL-1 study included patients with R/R FL following at least one prior line of treatment across a broad range of patient characteristics and disease risk factors. Among patients who were treated with EPKINLY + $R^2$ at the second planned interim analysis (median follow-up, 14.8 months), 83% achieved a complete response (CR) (n=201/243, 95% CI: 77.4, 87.3) compared to a 50% CR rate among patients treated with $R^2$ (n=122/245, 95% CI: 43.4, 56.2). The 12-month duration of response (DOR) was 89% (95% CI: 83.6, 93.0) versus 49% (95% CI: 38.8, 57.5) for patients treated with EPKINLY + $R^2$ and $R^2$, respectively.

The safety profile of EPKINLY + $R^2$ in the EPCORE FL-1 study was consistent with the known safety profiles of the individual regimens (epcoritamab and $R^2$). Grade 3 or 4 treatment-emergent adverse events (TEAE) were reported in 90.1% of patients treated with EPKINLY + $R^2$ compared to 67.6% of patients treated with $R^2$, the difference being primarily driven by higher rates of Grade 3 or 4 neutropenia (68.7% vs. 42.0%) and infections (33.3% vs. 15.1%). Fatal TEAEs occurred in 1.6% of patients treated with EPKINLY + $R^2$ compared to 3.8% patients treated with $R^2$. TEAEs leading to discontinuation occurred in 18.9% and 12.2% of patients treated with EPKINLY + $R^2$ and $R^2$, respectively. With the three step-up dosing regimen, CRS events were low grade and occurred in 26.3% of patients (21.2% Grade 1, 5.3% Grade 2).

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"The pivotal results from the EPCORE FL-1 trial demonstrate the potential of epcoritamab, in combination with established therapies, to enable earlier intervention across sites of care and deliver improved outcomes for patients with relapsed or refractory follicular lymphoma," said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. "We remain committed to developing epcoritamab, as a monotherapy and in combination, as a potential core therapy for B-cell malignancies and as a therapeutic innovation that can shift the treatment paradigm."

In November 2025, the U.S. Food and Drug Administration (FDA) approved the combination of EPKINLY + $R^2$ for the treatment of patients with relapsed or refractory FL after one or more lines of systemic therapy. EPKINLY is also approved in the U.S. to treat adults with relapsed/refractory FL after two or more prior treatments.

**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). Patients were randomized to receive EPKINLY in combination with rituximab and lenalidomide (n=243) or rituximab and lenalidomide alone (n=245). Patients received EPKINLY in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurred first. Efficacy was established based on the dual primary endpoints of progression free survival (PFS) and overall response rate (ORR) determined by Lugano 2014 criteria as assessed by Independent Review Committee (IRC). Additional efficacy outcome measures include complete response (CR) and duration of response (DOR).

**About Follicular Lymphoma (FL)**
Follicular lymphoma (FL) is typically an indolent, or slow-growing, form of non-Hodgkin lymphoma (NHL), that arises from B-lymphocytes. The second most common form of NHL, FL accounts for 20-30% of all NHL cases and is diagnosed in approximately 15,000 people in the U.S. every year.[i,ii] FL is considered incurable with current standard of care therapies.[iii] Patients often relapse, and with each relapse the remission and time to next treatment shorten.[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% of FL patients.[v]

**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. 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 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 four ongoing Phase 3, open-label, randomized trials, among them a trial evaluating epcoritamab as a monotherapy in patients with R/R

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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 $R^2$ 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®.

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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*This Media Release 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 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.*



[i] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed November 2025.
[ii] Leukemia & Lymphoma Society. https://www.lls.org/research/follicular-lymphoma-fl. Accessed November 2025.

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[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] 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.
[v] 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.
[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.