# Genmab Announces EPKINLY® (epcoritamab-bysp) in Combination with Rituximab and Lenalidomide Approved by the U.S. Food and Drug Administration for the Treatment of Relapsed or Refractory Follicular Lymphoma

## Company Announcement

- **EPKINLY plus rituximab and lenalidomide (EPKINLY + R²) is the first and only bispecific-based therapy approved by the FDA for follicular lymphoma in the second-line setting**
- **In the Phase 3 EPCORE® FL-1 trial, fixed duration EPKINLY + R² demonstrated significantly superior progression-free survival and overall response rates compared to standard of care R², with approximately three out of four patients achieving a complete response**
- **This approval marks the third indication for EPKINLY and the first-ever FDA approval for a bispecific combination therapy in the lymphoma space**

**COPENHAGEN, Denmark; November 18, 2025 – Genmab A/S (Nasdaq: GMAB) announced today that EPKINLY® (epcoritamab-bysp) in combination with rituximab and lenalidomide (EPKINLY + R²) was approved by the U.S. Food and Drug Administration (FDA) for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL)**. The approval is based on results from the pivotal Phase 3 EPCORE® FL-1 study that evaluated fixed duration EPKINLY + R² compared to standard of care R².[i]

In the study, treatment with fixed duration EPKINLY + R² reduced the risk of disease progression or death by 79% (HR 0.21, 95% CI: 0.13-0.33, p<0.0001) compared to R². Median progression-free survival (PFS) was not reached (NR) among patients treated with EPKINLY + R² (95% CI: 21.9-NR) compared to 11.2 months for patients treated with R² (95% CI: 10.5-NR). Among patients who were treated with EPKINLY + R², 89% responded to treatment (n=216/243, 95% CI: 84-93, p<0.0001) and 74% achieved a complete response (CR) (n=181/243, 95% CI: 69-80). This is compared to a 74% overall response rate (n=181/245, 95% CI: 68-79) and 43% CR rate among patients treated with R² (n=106/245, 95% CI: 37-50).[i] The Phase 3 EPCORE FL-1 study included patients with relapsed or recurrent FL following at least one prior line of treatment across a broad range of patient characteristics and disease risk factors.

The safety profile of EPKINLY + R² in the EPCORE FL-1 study was generally consistent with the known safety profiles of the individual regimens (epcoritamab and R²). The most common (≥ 20%) adverse reactions in patients who received EPKINLY + R² were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, cytokine release syndrome (CRS), pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) were decreased neutrophil count, lymphocyte count, and platelets. CRS occurred in 24% of patients at the recommended 3 step-up dosing schedule, and was primarily low grade (19% Grade 1, 5% Grade 2). A single event of immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in one patient, grade 1 (0.8%). The prescribing information has a Boxed Warning for serious or fatal CRS and ICANS. Warnings and precautions include infections, cytopenias, and embryo-fetal toxicity. Please see additional Important Safety Information below.[i]

“Recurrent follicular lymphoma can be an incurable, complex, and persistent disease, creating a clear need for additional treatments that can change its course earlier in the treatment journey,” said Lorenzo Falchi, M.D., Lymphoma Specialist, Department of Medicine, Memorial Sloan Kettering Cancer Center. “The results shown with EPKINLY + R² in the EPCORE FL-1 study are incredibly meaningful, demonstrating durable responses compared to patients treated with R² alone. These data, delivered by a regimen that’s chemotherapy-free and can be administered in the outpatient setting, suggest that EPKINLY + R² could potentially become a new standard of care.”

FL is typically a slow-growing form of non-Hodgkin lymphoma (NHL) that impacts approximately 15,000 new patients per year in the U.S..[ii,iii] The disease is considered incurable with current standard of care

therapies.[iv] Patients with FL often relapse, and in some cases, the disease can transform into a more aggressive form of NHL called diffuse large B-cell lymphoma (DLBCL).[v]

"Today's milestone marks meaningful progress for people living with follicular lymphoma. With a bispecific-based therapy that can be administered in a variety of medical settings, patients have the possibility of accessing this treatment at sites of care closer to where they live," said Meghan Gutierrez, Chief Executive Officer, Lymphoma Research Foundation.

EPKINLY + $R^2$ was previously granted Breakthrough Therapy Designation (BTD) by the FDA for the treatment of R/R FL. This designation is granted to investigational medicines for serious or life-threatening diseases in cases where preliminary clinical evidence shows that the therapy may provide substantial improvements over available therapies.

"The FDA approval of EPKINLY + $R^2$ is an important advancement for patients with follicular lymphoma, enabling treatment at initial recurrence when more effective intervention is needed," said Judith Klimovsky, M.D., Executive Vice President & Chief Development Officer, Genmab. "This milestone also underscores EPKINLY's potential as the core therapy for B-cell malignancies, demonstrating benefit in combination and earlier disease, and building on its established role as a single agent option in later lines of treatment."

In June 2024, EPKINLY monotherapy was granted accelerated approval by the FDA for the treatment of R/R FL following two or more lines of systemic therapy. With the results from the confirmatory Phase 3 EPCORE FL-1 study, the FDA has also converted the accelerated approval into a full approval.

Data from the Phase 3 EPCORE FL-1 study will be presented at the Annual Meeting and Exposition of the American Society of Hematology in December.

**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).

**EPKINLY® (epcoritamab-bysp) U.S. INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**What is EPKINLY?**
EPKINLY is a prescription medicine used to treat adults with:

- certain types of diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma that has come back (relapsed) or that did not respond (refractory), after 2 or more treatments.
    - EPKINLY for the treatment of DLBCL is approved based on patient response data. Studies are ongoing to confirm the clinical benefit of EPKINLY.
- follicular lymphoma (FL) that has come back or that did not respond to previous treatment, together with lenalidomide and rituximab

# Genmab Announces EPKINLY® (epcoritamab-bysp) in Combination with Rituximab and Lenalidomide Approved by the U.S. Food and Drug Administration for the Treatment of Relapsed or Refractory Follicular Lymphoma

- follicular lymphoma (FL) that has come back or that did not respond after receiving 2 or more treatments.

It is not known if EPKINLY is safe and effective in children.

**Important Warnings—EPKINLY can cause serious side effects, including:**

- **Cytokine release syndrome (CRS)**, which is common during treatment with EPKINLY and can be serious or lead to death. To help reduce your risk of CRS, you will receive EPKINLY on a step-up dosing schedule (when you receive 2 or 3 smaller step-up doses of EPKINLY before your first full dose during your first cycle of treatment), and you may also receive other medicines before and for 3 days after receiving EPKINLY. If your dose of EPKINLY is delayed for any reason, you may need to repeat the step-up dosing schedule.
- **Neurologic problems** that can be serious, and can be life-threatening, and lead to death. Neurologic problems may happen days or weeks after you receive EPKINLY.

**People with DLBCL or high-grade B-cell lymphoma** should be hospitalized for 24 hours after receiving their first full dose of EPKINLY on Day 15 of Cycle 1 due to the risk of CRS and neurologic problems.

**People with follicular lymphoma (FL)** may need to be hospitalized after receiving their first full dose of EPKINLY on Day 22 of Cycle 1 due to the risk of CRS.

**Tell your healthcare provider or get medical help right away** if you develop a fever of 100.4°F (38°C) or higher; dizziness or lightheadedness; trouble breathing; chills; fast heartbeat; feeling anxious; headache; confusion; shaking (tremors); problems with balance and movement, such as trouble walking; trouble speaking or writing; confusion and disorientation; drowsiness, tiredness or lack of energy; muscle weakness; seizures; or memory loss. **These may be symptoms of CRS or neurologic problems.** If you have any symptoms that impair consciousness, **do not** drive or use heavy machinery or do other dangerous activities until your symptoms go away.

**EPKINLY can cause other serious side effects, including:**

- **Infections** that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment and treat you as needed if you develop an infection. You should receive medicines from your healthcare provider before you start treatment to help prevent infection. Tell your healthcare provider right away if you develop any symptoms of infection during treatment, including fever of 100.4°F (38°C) or higher, cough, chest pain, tiredness, shortness of breath, painful rash, sore throat, pain during urination, feeling weak or generally unwell, or confusion.
- **Low blood cell counts,** which can be serious or severe. Your healthcare provider will check your blood cell counts during treatment. EPKINLY may cause low blood cell counts, including low white blood cells (neutropenia and lymphopenia), which can increase your risk for infection; low red blood cells (anemia), which can cause tiredness and shortness of breath; and low platelets (thrombocytopenia), which can cause bruising or bleeding problems.

Your healthcare provider will monitor you for symptoms of CRS, neurologic problems, infections, and low blood cell counts during treatment with EPKINLY. Your healthcare provider may temporarily stop or completely stop treatment with EPKINLY if you develop certain side effects.

**Before you receive EPKINLY, tell your healthcare provider about all your medical conditions, including if you** have an infection, are pregnant or plan to become pregnant, or are breastfeeding or

# Genmab Announces EPKINLY® (epcoritamab-bysp) in Combination with Rituximab and Lenalidomide Approved by the U.S. Food and Drug Administration for the Treatment of Relapsed or Refractory Follicular Lymphoma

plan to breastfeed. If you receive EPKINLY while pregnant, it may harm your unborn baby. **If you are a female who can become pregnant**, your healthcare provider should do a pregnancy test before you start treatment with EPKINLY and you should use effective birth control (contraception) during treatment and for 4 months after your last dose of EPKINLY. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with EPKINLY. Do not breastfeed during treatment with EPKINLY and for 4 months after your last dose of EPKINLY.

**The most common side effects of EPKINLY when used alone in DLBCL or high-grade B-cell lymphoma or FL include** CRS, injection site reactions, tiredness, muscle and bone pain, fever, diarrhea, COVID-19, rash, and stomach-area (abdominal) pain. **The most common severe abnormal laboratory test results with EPKINLY when used alone** include decreased white blood cells, decreased red blood cells, and decreased platelets.

**The most common side effects of EPKINLY when used together with lenalidomide and rituximab in FL include** rash**,** upper respiratory tract infections, tiredness, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. **The most common severe abnormal laboratory test results with EPKINLY when used together with lenalidomide and rituximab** include decreased white blood cells and decreased platelets.

These are not all of the possible side effects of EPKINLY. Call your doctor for medical advice about side effects.

You are encouraged to report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to Genmab US, Inc. at 1-855-4GENMAB (1-855-443-6622).

**Please see Medication Guide, including Important Warnings.**

**Helping Patients Access Care**
Genmab strives to positively impact patients' lives, and we're committed to helping ensure our medicines reach the people who need them. We understand the impact that cancer can have, and so we empower patients and their care partners to take ownership of their treatment journey, offering support every step of the way. *MyNavCare Patient Support*™ by Genmab offers resources and services, from financial information to ongoing support, to help eligible patients access their Genmab medication and navigate their treatment journey. *MyNavCare* is available now to patients who have been prescribed EPKINLY. Patients, care partners, and healthcare providers interested in learning more about *MyNavCare* can visit www.MyNavCare.com or call 1-866-NAV-CAR1 (1-866-628-2271).

**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.[ii,iii] FL is considered incurable with current standard of care therapies.[iv] Patients often relapse, and with each relapse the remission and time to next treatment shorten.[vi] 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 EPKINLY® (epcoritamab-bysp)**
EPKINLY® (epcoritamab-bysp) 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.[vii]

Epcoritamab (approved under the brand name EPKINLY in countries including the U.S. and Japan, and as TEPKINLY® in the European Union) has received regulatory approval in certain lymphoma indications in more than 65 countries. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. The companies will share commercialization responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Both companies will pursue additional international regulatory approvals for the 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 additional 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 immunochemotherapy (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 ($R^2$) 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.

**Contact:**
Caitlin Craparo, Vice President, Global Communications & Corporate Affairs
T: +1 609 255 7397; E: cacr@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*

# Genmab Announces EPKINLY® (epcoritamab-bysp) in Combination with Rituximab and Lenalidomide Approved by the U.S. Food and Drug Administration for the Treatment of Relapsed or Refractory Follicular Lymphoma

*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.*

*Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; HexaBody®; DuoHexaBody®, HexElect® and KYSO®.*

---

[i] EPKINLY (epcoritamab-bysp) [package insert]. Copenhagen, Denmark: Genmab, 2025.
[ii] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed November 2025.
[iii] Leukemia & Lymphoma Society. https://www.lls.org/research/follicular-lymphoma-fl. Accessed November 2025.
[iv] 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.
[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] 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.
[vii] 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.