Genmab Announces TEPKINLY® (epcoritamab) in Combination with Lenalidomide and Rituximab is Approved by the European Commission for the Treatment of Relapsed or Refractory Follicular Lymphoma

Media Release

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- **TEPKINLY® (epcoritamab) plus lenalidomide and rituximab (R^2) is the first and only bispecific-based therapy approved in Europe for the treatment of follicular lymphoma in the second-line setting, offering a chemotherapy-free option**
- **In the Phase 3 EPCORE® FL-1 trial, fixed-duration TEPKINLY + R^2 demonstrated significantly superior progression-free survival and overall response rates compared to R^2, with approximately three out of four patients achieving a complete response**

Genmab A/S (Nasdaq: GMAB) announced today that the European Commission (EC) granted marketing authorization for TEPKINLY® (epcoritamab) in combination with lenalidomide and rituximab (TEPKINLY + R^2) for the treatment of 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 trial that evaluated fixed-duration TEPKINLY + R^2 compared to standard of care R^2.

“Follicular lymphoma is a persistent form of cancer that remains incurable, which means patients need more treatment options. Patients often relapse and experience shorter remissions and have fewer treatment options each time the disease returns,” said Catherine Thieblemont, M.D., Ph.D., head of the hemato-oncology department, Paris Cité University, Hôpital Saint-Louis Assistance-Publique-Hopitaux de Paris (APHP) in Paris. “The results shown in the EPCORE FL-1 trial are clinically meaningful, demonstrating the potential for TEPKINLY + R^2 to change the treatment paradigm for patients, offering the chance at a durable response with a chemotherapy-free option.”

The marketing authorization is supported by data from the Phase 3 EPCORE FL-1 trial, an open-label interventional trial to evaluate the safety and efficacy of TEPKINLY + R^2 compared to R^2 alone in patients with R/R FL. The study demonstrated TEPKINLY + R^2 reduced the risk of disease progression or death by 79% (HR 0.21, 95% CI: 0.13 - 0.33, p<0.0001) compared to R^2 alone. The overall response rate (ORR) in patients treated with TEPKINLY + R^2 was 96% (95% CI: 90.2, 98.6) compared to 81% in patients treated with R^2 (95% CI: 72.7, 87.7; p<.0001). Among patients who were treated with TEPKINLY + R^2, 74% achieved a complete response (CR) (n=181/243, 95% CI: 68.5, 79.8) compared to a 43% CR rate among patients treated with R^2 (n=106/245, 95% CI: 37.0, 49.7).

The safety profile of TEPKINLY + R^2 in the EPCORE FL-1 study was consistent with the known safety profiles of the individual regimens (epcoritamab and R^2). In the trial, the most common (≥ 20%) adverse reactions were neutropenia, rash, upper respiratory tract infections, fatigue, diarrhea, injection site reactions, anemia, constipation, thrombocytopenia, cytokine release syndrome (CRS), hypogammaglobulinemia, COVID-19, pyrexia, and pneumonia. Serious adverse reactions occurred in 44% of patients who received epcoritamab in combination with lenalidomide and rituximab. Serious adverse reactions in ≥ 5% of patients included CRS, pneumonia, COVID-19, and febrile neutropenia.

"The marketing authorization of TEPKINLY + R^2 by the European Commission represents a pivotal moment for individuals living with follicular lymphoma, providing a treatment option at first relapse, when effective intervention is critical,” said Judith Klimovsky, M.D., Executive Vice President & Chief Development Officer of Genmab. “This milestone reinforces TEPKINLY's potential as a core therapy across B-cell malignancies, validating its use in combination and earlier follicular lymphoma settings, while building upon its established efficacy as a monotherapy in advanced disease."

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FL is typically a slow-growing form of non-Hodgkin lymphoma (NHL) that arises from B-cell lymphocytes. FL is the second most common form of NHL overall, accounting for 20-30 percent of all NHL cases.[i] FL incidence is significantly higher in European populations, 11-29 percent, compared to non-European populations, 2-18 percent.[ii] FL is considered incurable, and there is no standard of care treatment for third-line or later FL.[i,iii] Patients who achieve remission also often experience relapse.[iv,v, vi]

"A diagnosis of follicular lymphoma can bring a relentless cycle of disease recurrence and treatment," said Mitchell Smith, M.D., Ph.D., Chief Medical Officer of the Follicular Lymphoma Foundation. "The approval of epcoritamab now in combination with R^2 in Europe is a welcome advance that will bring an innovative treatment option and hope to the follicular lymphoma community."

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 lenalidomide and rituximab (R^2) versus R^2 alone in patients with relapsed/refractory (R/R) follicular lymphoma (FL). 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. Patients were randomized to receive epcoritamab in combination with R^2 (n=243) or R^2 alone (n=245). Patients received epcoritamab 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). The pivotal Phase 3 EPCORE FL-1 trial results were published in *The Lancet* in January 2026.

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 European Union) has received regulatory approval in certain lymphoma indications in more than 65 territories. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. The companies 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 relapsed or refractory (R/R) follicular lymphoma (FL) indication and additional approvals for the R/R diffuse large B-cell lymphoma (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 several Phase 3, open-label, randomized trials, including a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL (NCT05578976), a trial evaluating epcoritamab in combination with lenalidomide compared to chemotherapy infusion in patients with R/R DLBCL (NCT06508658), and a trial evaluating epcoritamab in combination with lenalidomide and rituximab (R^2) compared to chemoimmunotherapy in patients with previously untreated FL (NCT06191744). The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit www.clinicaltrials.gov for more information.

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About Genmab
Genmab is an international biotechnology company dedicated to improving the lives of people with cancer and other serious diseases through innovative antibody medicines. For over 25 years, its passionate, innovative and collaborative team has advanced a broad range of antibody-based therapeutic formats, including bispecific antibodies, antibody–drug conjugates (ADCs), immune-modulating antibodies and other next-generation modalities. Genmab's science powers eight approved antibody medicines, and the company is advancing a strong late-stage clinical pipeline, including wholly owned programs, with the goal of delivering transformative medicines to patients.

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] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed May 2026.
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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] Lymphoma Research Foundation official website. https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/follicular-lymphoma/relapsedfl/. Accessed May 2026.
[v] Rivas-Delgado, A, Magnano, L, Moreno-Velázquez, 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, Hiemstra IH, de Jong B, 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.