U.S. FDA Accepts for Priority Review the Supplemental Biologics License Application for Epcoritamab (EPKINLY®) for Difficult-to-Treat Relapsed or Refractory Follicular Lymphoma

Media Release

COPENHAGEN, Denmark; February 27, 2024

- **FDA grants Priority Review with target action date of June 28, 2024**
- **Application based on results from Phase 1/2 EPCORE™ NHL-1 trial demonstrating clinically meaningful treatment responses in difficult-to-treat patients with relapsed or refractory (R/R) follicular lymphoma (FL)**
- **sBLA submission demonstrates Genmab's commitment to exploring potential utility of epcoritamab across B-cell malignancies**

Genmab A/S (Nasdaq: GMAB) and AbbVie (NYSE: ABBV) today announced the U.S. Food and Drug Administration (FDA) granted Priority Review for the supplemental Biologics License Application (sBLA) for epcoritamab-bysp, a T-cell engaging bispecific antibody administered subcutaneously, for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy.

The FDA grants Priority Review to investigational therapies that, if approved, may offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. This designation shortens the review period to six months compared to 10 months for Standard Review.[i] The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2024.

"While treatment for patients with relapsed and refractory follicular lymphoma has progressed, there remains an urgent need for new treatment options, particularly for patients who are considered difficult to treat due to relapse following standard therapies and other poor prognostic factors," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "The acceptance of the epcoritamab application for Priority Review marks an important milestone toward potentially providing a new treatment option to patients affected by R/R follicular lymphoma. Together with AbbVie, we look forward to working with the FDA during the review and remain committed to developing epcoritamab as a potential future core therapy for B-cell malignancies."

The sBLA is based on results from the Phase 1/2 EPCORE™ NHL-1 clinical trial, which demonstrated high overall and complete responses in patients with R/R FL treated with epcoritamab. Data from the FL cohort of the trial were presented at the Annual Meeting and Exposition of the American Society of Hematology (ASH) in December 2023. The FDA previously granted Breakthrough Therapy Designation (BTD) to epcoritamab for the treatment of adult patients with R/R FL after two or more lines of systemic therapy. The application for BTD included additional data from the dose optimization part of EPCORE NHL-1.

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.

About the Phase 1/2 EPCORE™ NHL-1 Trial
EPCORE™ NHL-1 is an open-label, multi-center safety and preliminary efficacy trial of epcoritamab that consists of three parts: a dose escalation part; an expansion part; and an optimization part. The trial was designed to evaluate subcutaneous epcoritamab in patients with relapsed, progressive or refractory

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CD20+ mature B-cell non-Hodgkin's lymphoma (B-NHL), including FL. In the expansion part, additional patients were enrolled to further explore the safety and efficacy of epcoritamab in three cohorts of patients with different types of relapsed/refractory B-NHLs who have limited therapeutic options. The optimization part evaluates the potential for alternative step-up dosing regimens to help further minimize Grade 2 cytokine release syndrome (CRS) and mitigate Grade ≥3 CRS. The primary endpoint of the expansion part was ORR as assessed by an IRC. Secondary efficacy endpoints included duration of response, complete response rate, duration of complete response, progression-free survival, and time to response as determined by the Lugano criteria. Overall survival, time to next therapy, and rate of minimal residual disease negativity were also evaluated as secondary efficacy endpoints. The primary endpoint of the optimization part was the rate of ≥ Grade 2 CRS events and all grade CRS events from first dose of epcoritamab through 7 days following administration of the second full dose of epcoritamab.

About Follicular Lymphoma (FL)
FL is typically an indolent (or slow-growing) form of non-Hodgkin's lymphoma (NHL) that arises from B-lymphocytes.[ii] FL is the second most common form of NHL overall, accounting for 20-30 percent of all NHL cases, and represents 10-20 percent of all lymphomas in the western world.[iii,iv] Although FL is an indolent lymphoma, it is considered incurable with conventional therapy and patients who achieve remission also often experience relapse.[v,vi,vii] Additionally, with each relapse the remission and time to next treatment is shorter[viii], adding increased cost to the health system and negatively impacting the patient's quality of life.[ix]

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.[x]

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. Use of epcoritamab in FL is not approved in the U.S. or in the EU or in any other territory. 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.

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 three ongoing phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL (NCT: 04628494) compared to investigators choice chemotherapy, a phase 3 trial evaluating epcoritamab in combination with R-CHOP in adult participants with newly diagnosed DLBCL (NCT: 05578976), and a phase 3, open-label clinical trial evaluating epcoritamab in combination with rituximab and lenalidomide in patients with R/R FL (NCT: 05409066). Epcoritamab is not approved to treat newly diagnosed patients with DLBCL or FL. The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit clinicaltrials.gov for more information.

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About Genmab
Genmab is an international biotechnology company with a core purpose guiding its unstoppable team to strive towards improving the lives of patients through innovative and differentiated antibody therapeutics. For more than 20 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational research and data sciences, which has resulted in a proprietary pipeline including bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. To help develop and deliver novel antibody therapies to patients, Genmab has formed 20+ strategic partnerships with biotechnology and pharmaceutical companies. 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 locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit Genmab.com and follow us on Twitter.com/Genmab.

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[i] U.S. Food and Drug Administration official website. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review. Accessed February 2024.
[ii] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed February 2024.
[iii] Ma S. Risk factors of follicular lymphoma. *Expert Opin Med Diagn.* 2012;6:3232333. doi: 10.1517/17530059.2012.686996.
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[vii] Lymphoma Research Foundation official website. https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/follicular-lymphoma/relapsedfl/. Accessed February 2024.
[viii] 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
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[x] 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.