



Genmab Announces U.S. Food and Drug Administration Accepts for Priority Review Biologics License Application (BLA) for Epcoritamab (DuoBody®-CD3xCD20) for the Treatment of Relapsed/Refractory Large B-Cell Lymphoma (LBCL)

Media Release

COPENHAGEN, Denmark; November 21, 2022

- **Epcoritamab BLA accepted for FDA Priority review; FDA action date is May 21, 2023**
- **Epcoritamab could become the first subcutaneous bispecific antibody approved for the treatment of LBCL**
- **BLA submission supported by positive EPCORE™ NHL-1 trial results**

[Genmab A/S](#) (Nasdaq: **GMAB) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) for subcutaneous epcoritamab (DuoBody®-CD3xCD20), an investigational bispecific antibody, for the treatment of patients with relapsed/refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of May 21, 2023.**

The BLA submission is based on safety and preliminary efficacy data from the LBCL cohort of the pivotal EPCORE™ NHL-1 open-label, multi-center phase 2 clinical trial evaluating epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-cell non-Hodgkin lymphoma (B-NHL). These [results](#) were presented in a late-breaking oral presentation as a part of the Presidential Symposium at the 27th Annual Meeting of the European Hematology Association (EHA2022), in Vienna, Austria.

“We are pleased that the BLA for epcoritamab has been accepted for Priority Review by the FDA, accelerating the pathway for approval and bringing us one step closer to potentially delivering a novel treatment option to relapsed and refractory LBCL patients who are in need of additional treatment options,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “Together with our partner, AbbVie, we recognize the unmet need for safe, effective and accessible treatments for patients with B-cell malignancies and we believe that epcoritamab has the potential to become a core therapy in this patient population.”

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. The companies are committed to evaluating epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies, including an ongoing phase 3, open-label, randomized clinical trial evaluating epcoritamab as a monotherapy in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) (NCT: 04628494) and a phase 3, open-label clinical trial evaluating epcoritamab in combination in patients with relapsed/refractory follicular lymphoma (FL) (NCT: 05409066).

In October 2022, the European Medicines Agency [validated](#) for review a Marketing Authorization Application (MAA) for epcoritamab for the treatment of patients with relapsed/refractory DLBCL – a major subtype of LBCL – after two or more lines of systemic therapy.

Based on the existing agreement, this milestone triggers a USD 80 million milestone payment from AbbVie. The milestone payment will not impact Genmab's 2022 financial guidance provided on November 9, 2022.

About Large B-cell Lymphoma (LBCL) and Diffuse Large B-cell Lymphoma (DLBCL)

Large B-cell lymphoma (LBCL) is a fast-growing type of non-Hodgkin's lymphoma (NHL), a cancer that develops in the lymphatic system and affects B-cell lymphocytes, a type of white blood cell. There are an estimated 150,000 new LBCL cases each year globally.^{1,2} Diffuse large B-cell lymphoma (DLBCL) is a fast-growing type of NHL³ and the most common type of NHL worldwide, accounting for approximately 31 percent of all NHL cases.² DLBCL can arise in lymph nodes as well as in organs outside of the lymphatic system, occurs more commonly in the elderly and is slightly more prevalent in men.¹

About the EPCORE™ NHL-1 Trial

EPCORE™ NHL-1 is an open-label, multi-center safety and preliminary efficacy trial of epcoritamab including a phase 1 first-in-human, dose escalation part; a phase 2 expansion part; and an optimization part. The trial was designed to evaluate subcutaneous epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-NHL, including LBCL and DLBCL. Data from the dose escalation part of the study, which determined the recommended phase 2 dose, were published in [The Lancet](#) in 2021. In the phase 2 expansion part, additional patients are treated with epcoritamab to further explore the safety and efficacy of epcoritamab in patients with different types of relapsed/refractory B-NHLs who had limited therapeutic options.

The primary endpoint of the phase 2 expansion part was overall response rate (ORR) as assessed by an IRC. Secondary efficacy endpoints included duration of response, complete response rate, progression-free survival, overall survival, time to response, time to next therapy, and rate of minimal residual disease negativity.

About Epcoritamab

Epcoritamab is an investigational IgG1-bispecific antibody created using Genmab's proprietary DuoBody technology. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response towards 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.⁴ CD20 is expressed on B-cells and a clinically validated therapeutic target in many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.^{5,6}

About Genmab

Genmab is an international biotechnology company with a core purpose to improve the lives of people with cancer. For more than 20 years, Genmab's vision to transform cancer treatment has driven its passionate, innovative and collaborative teams to invent next-generation antibody technology platforms and leverage translational research and data sciences, fueling multiple differentiated cancer treatments that make an impact on people's lives. To develop and deliver novel therapies to patients, Genmab has formed 20+ strategic partnerships with biotechnology and pharmaceutical companies. Genmab's proprietary pipeline includes bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates.

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](https://twitter.com/Genmab).

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Genmab Forward-Looking Statements

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 pre-clinical 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.

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¹ Sehn, Salles. "Diffuse Large B-Cell Lymphoma." N Engl J Med. 2021;384:842-858. DOI: 10.1056/NEJMra2027612

² Martelli, Ferreri, Agostinelli, et al. "Diffuse large B-cell lymphoma." Crit Rev Oncol Hematol. 2013;87(2):146-71. DOI: 10.1016/j.critrevonc.2012.12.009

³ "Diffuse Large B-Cell Lymphoma." Lymphoma Research Foundation, <https://www.lymphoma.org/aboutlymphoma/nhl/dlbc/>. Date accessed: October 26, 2022.

⁴ Engelberts 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

⁵ Rafiq, Butchar, Cheney, et al. "Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties." J. Immunol. 2013;190(6):2702-2711. DOI: 10.4049/jimmunol.1202588

⁶ Singh, Gupta, Almasan. "Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response." J Cancer Sci Ther. 2015;7(11):347-358. DOI: 10.4172/1948-5956.1000373