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

Company Announcement

COPENHAGEN, Denmark; June 30, 2022 – Genmab A/S (Nasdaq: GMAB) today announced its intent to submit a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for subcutaneous epcoritamab (DuoBody®-CD3xCD20), an investigational bispecific antibody, for the treatment of patients with relapsed/refractory large B-cell lymphoma (LBCL), in the second half of 2022.

The BLA submission is supported by results from the large b-cell lymphoma (LBCL) cohort of the pivotal EPCORE™ NHL-1 open-label, multi-center trial evaluating the safety and preliminary efficacy of epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-cell non-Hodgkin lymphoma (B-NHL). In April 2022, Genmab and AbbVie announced the topline results from EPCORE™ NHL-1 trial. In June 2022, primary results were presented in a late-breaking oral presentation as part of the Presidential Symposium at the 27th Annual Meeting of the European Hematology Association (EHA2022) in Vienna, Austria.

“Relapsed or refractory large B-cell lymphoma is often difficult to treat, and patients are in need of novel therapies that are effective, tolerable and accessible,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “The results from the EPCORE NHL-1 trial, and other clinical trials evaluating epcoritamab in a variety of patients and treatment settings, have demonstrated that epcoritamab has the potential to offer people living with LBCL a new therapeutic advance with a manageable safety profile.”

Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. 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 trial evaluating epcoritamab as a monotherapy in patients with relapsed/refractory DLBCL (NCT: 04628494).

About Large B-cell Lymphoma (LBCL)
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. LBCL includes DLBCL, which is the most common type of NHL worldwide and accounts for approximately 31 percent of all NHL cases.[i,ii,iii,iv]

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.

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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.[v] 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.[vi,vii]

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.

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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.

[i] "Diffuse Large B-Cell Lymphoma." Lymphoma Research Foundation, https://www.lymphoma.org/aboutlymphoma/nhl/dlbcl/. Date accessed: 7 June 2022.
[ii] "Non-Hodgkin Lymphoma." Lymphoma Research Foundation, https://lymphoma.org/aboutlymphoma/nhl/. Date accessed: 7 June 2022.

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[iii] Sehn, Salles. "Diffuse Large B-Cell Lymphoma." N Engl J Med. 2021;384:842-858. DOI: 10.1056/NEJMra2027612
[iv] 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
[v] 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
[vi] 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
[vii] 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