Genmab Announces Submission of Japan New Drug Application (JNDA) for Epcoritamab (DuoBody®-CD3xCD20) for the Treatment of Relapsed/Refractory Large B-Cell Lymphoma (LBCL)

Media Release

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- **JNDA submission supported by results of Japanese and global phase 2 clinical trials evaluating epcoritamab in patients with mature B-cell non-Hodgkin's lymphoma (NHL), including relapsed/refractory large B-cell lymphoma (LBCL)**

Genmab A/S (Nasdaq: GMAB) today announced that the company has submitted a Japan new drug application (JNDA) to the Ministry of Health, Labor and Welfare (MHLW) of Japan for subcutaneous epcoritamab (DuoBody®-CD3xCD20), an investigational bispecific antibody, for the treatment of patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after two or more lines of systemic therapy.

The JNDA submission is supported by the EPCORE™ NHL-3, open-label, multi-center, phase 2 trial (GCT3013-04) evaluating the safety and preliminary efficacy of epcoritamab in adult patients in Japan with relapsed, progressive or refractory CD20+ mature B-cell non-Hodgkin lymphoma (B-NHL), as well as results from the global EPCORE™ NHL-1 open-label, multi-center, phase 2 trial (GCT3013-01) evaluating epcoritamab in the same patient population.

"With this regulatory submission, we are one step closer to potentially delivering epcoritamab as a new therapeutic option to patients in Japan with relapsed and refractory LBCL who are in need of alternative treatments," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "Genmab and our partner AbbVie believe that epcoritamab has the potential to become a core therapy for patients around the world with B-cell malignancies and we are committed to progressing the comprehensive development program evaluating epcoritamab across a broad range of B-cell lymphomas."

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) (EPCORE™ DLBCL-1, NCT04628494) and a phase 3, open-label clinical trial evaluating epcoritamab in combination in patients with relapsed/refractory follicular lymphoma (FL) (EPCORE™ FL-1, NCT05409066).

Genmab recently announced that the Biologics License Application (BLA) for epcoritamab for the treatment or R/R LBCL was accepted for Priority Review by the U.S. Food and Drug Administration (FDA), with an FDA action date of May 21, 2023. Additionally, the European Medicines Agency recently validated the Marketing Authorization Application (MAA) for epcoritamab for the treatment of adult patients with R/R DLBCL after two or more lines of systemic therapy.

About Large B-cell Lymphoma (LBCL)
Large B-cell lymphoma (LBCL) is a fast-growing type of B-cell non-Hodgkin's lymphoma (B-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]

About the EPCORE NHL-3 Trial (GCT3013-04)
EPCORE NHL-3 (GCT3013-04) is an open-label, multi-center safety and preliminary efficacy trial of epcoritamab including a phase 1 first-in-human, dose escalation part; and a phase 2 expansion part. The trial was designed to evaluate subcutaneous epcoritamab in Japanese patients with relapsed, progressive or refractory mature B-NHL, including DLBCL. In the phase 2 expansion part, additional patients are treated with epcoritamab to further explore the safety and efficacy of epcoritamab in patients with relapsed/refractory DLBCL and F who had limited therapeutic options.

About the EPCORE NHL-1 Trial (GCT3013-01)
EPCORE NHL-1 (GCT3013-01) 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 independent review committee (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.[3] 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.[4,5]

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.*

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