

Clinical Trial of Investigational Epcoritamab (DuoBody®-CD3xCD20) in Patients with Relapsed/Refractory B-cell non-Hodgkin's Lymphoma (B-NHL) Published in *The Lancet*

Media Release

- Phase 1/2 first-in-human (FIH) dose escalation and cohort expansion trial evaluating safety and preliminary efficacy of epcoritamab in patients with relapsed/refractory B-cell non-Hodgkin's lymphoma (B-NHL) published in *The Lancet*
- Results also presented during oral session at the 16th Annual International Conference on Malignant Lymphoma (ICML) and as a poster at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2021 European Hematology Association (EHA) Annual Meeting

Copenhagen, Denmark; North Chicago, Ill., September 9, 2021 – Genmab A/S (Nasdaq: GMA) and AbbVie (NYSE: ABBV) today announced *The Lancet* published the results of the dose escalation part of the phase 1/2 EPCORE™ NHL-1 first-in-human (FIH) dose escalation and cohort expansion clinical trial evaluating safety and preliminary efficacy of the investigational therapy epcoritamab (DuoBody®-CD3xCD20) in patients with relapsed/refractory B-cell non-Hodgkin's lymphoma (B-NHL). The full manuscript is available on *The Lancet's* [website](#). Epcoritamab is being co-developed by Genmab and AbbVie.

The FIH trial was designed to evaluate subcutaneous epcoritamab in patients with relapsed, progressive, or refractory CD20+ mature B-NHL, including diffuse large B-cell Lymphoma (DLCL) and follicular lymphoma (FL), to determine the maximum tolerated dose (MTD) and the recommended phase 2 dose (RP2D). In the dose escalation phase, patients received subcutaneous epcoritamab (doses ranged from 0.0128-60mg) for 28 days. The safety, antitumor activity, and immune biomarkers associated with epcoritamab treatment were assessed.¹

No dose-limiting toxicities were observed during the dose escalation, and 48mg was identified as the RP2D. Common adverse events (AEs) in patients with relapsed/refractory DLCL were pyrexia (69 percent), primarily associated with cytokine release syndrome (CRS) (59 percent, all grade 1-2), and injection site reactions (47 percent, all grade 1). One case of tumor lysis syndrome (TLS) was observed, (1 percent, grade 3). No grade 3 or above CRS events or discontinuations due to treatment-related AEs or death were observed.¹

Preliminary efficacy results reported in the trial were 88 percent overall response rate (ORR) and 38 percent complete response (CR) in patients with relapsed/refractory DLCL who received the RP2D of 48mg of (n=8) epcoritamab. Patients who were treated with 12-60mg of epcoritamab (n=22) achieved a 68 percent ORR and 45 percent CR. Additionally, patients with relapsed/refractory FL treated with 0.76-48mg of epcoritamab (n=10) achieved a 90 percent ORR and a 50 percent CR.¹

"The publication of these data in *The Lancet*, coupled with the presentation of the results at multiple medical congresses, demonstrate the importance of these early results and underscore the significant interest in the potential of next-generation antibody therapeutic options for patients diagnosed with hematologic malignancies, whose current treatments may not be providing benefit," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "Together with our partner, AbbVie, we are deeply committed to evaluating the safety and efficacy of epcoritamab in patients diagnosed with B-cell Lymphomas and other hematologic malignancies."

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"These initial trial results are encouraging, and their publication in *The Lancet* speaks to the strong interest from the clinical community in this important area of study," said Mohamed Zaki, M.D., Ph.D., vice president and head, global oncology development, AbbVie. "We look forward to further study epcoritamab in B-cell lymphomas and other hematologic malignancies, and continued pursuit of potential new treatment options for patients."

Results from this trial were also recently presented during an oral session at the 16th Annual International Conference on Malignant Lymphoma (ICML), held virtually June 18-22. The abstract is available for download via the [16-ICML Virtual Platform](#). Additionally, these results were presented as a poster at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, held virtually, June 4-8, and during the European Hematology Association (EHA) congress, held virtually, June 9-17. The posters are available for download via the [ASCO Meeting Library](#) and the [EHA Open Access Library](#).

About the EPCORE™ NHL-1 Trial

The dose escalation part of the EPCORE NHL-1 phase 1/2 clinical trial is evaluating epcoritamab in 68 patients with relapsed, progressive, or refractory B-cell non-Hodgkin's lymphoma (B-NHL), including DLBCL, FL, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, mantle cell lymphoma, small lymphocytic lymphoma and marginal zone lymphoma. The trial is an open-label, multi-center safety and preliminary efficacy trial of epcoritamab that consists of two parts: a phase 1 first-in-human (FIH), dose escalation part, and a phase 2 expansion part. Step-up dosing and standard prophylaxis were used to mitigate severity of cytokine release syndrome (CRS). The purpose of the escalation part is to determine the maximum tolerated dose and the recommended phase 2 dose (RP2D), as well as evaluate the safety profile of epcoritamab. In the expansion part, additional patients will be treated with epcoritamab with the RP2D to further explore the safety and efficacy of epcoritamab.

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 tumors to elicit an immune response towards malignant cells. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T cell mediated killing of lymphoma B cells.² CD20 is a clinically validated therapeutic target, and is expressed on many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.^{3,4} Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' broad oncology collaboration.

About Genmab

Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company 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](#).

About AbbVie

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AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on [Twitter](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

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Genmab Forward-Looking Statements

This Company Announcement 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 Company Announcement 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.

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody®; HexElect®; and UniBody®.

AbbVie Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits from AbbVie's acquisition of Allergan plc ("Allergan"), failure to promptly and effectively integrate Allergan's businesses, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry and the impact of public health outbreaks, epidemics or pandemics, such as COVID-19.

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Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2020 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

¹Hutchings M, Mous R, Clausen MR, et al. Dose escalation of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin lymphoma: an open-label, phase 1/2 study. *Lancet* 2021; published online Sept 8. [https://doi.org/10.1016/S0140-6736\(21\)00889-8](https://doi.org/10.1016/S0140-6736(21)00889-8).

²Engelbert 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 Feb;52: 102625. doi: 10.1016/j.ebiom.2019.102625. Epub 2020 Jan 23. PMID: 31981978; PMCID: PMC6992935.

³Rafiq, Sarwish, et al. "Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties." *Journal of Immunology* (Baltimore, Md. 1950), U.S. National Library of Medicine, 15 Mar. 2013, www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/.

⁴Singh, Vijay, et al. "Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response." *Journal of Cancer Science & Therapy*, U.S. National Library of Medicine, Nov. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/.