



## Genmab and AbbVie Announce Topline Results for Epcoritamab (DuoBody®-CD3xCD20) From Phase 1/2 Trial in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL)

April 13, 2022

### Company Announcement

- **Based on the topline results from the EPCORE™ NHL-1 clinical trial, Genmab and AbbVie will engage global regulatory authorities to discuss next steps**
- **Data from the clinical trial to be presented at a future medical meeting**
- **Large B-cell lymphoma (LBCL) is a common form of non-Hodgkin's lymphoma (NHL) and currently has limited treatment options**

**COPENHAGEN, Denmark and NORTH CHICAGO, Illinois; APRIL 13, 2022** – Genmab A/S (Nasdaq: GMAB) and AbbVie (NYSE: ABBV) announced today topline results from the first cohort of the EPCORE™ NHL-1 phase 1/2, clinical trial evaluating epcoritamab (DuoBody®-CD3xCD20), an investigational subcutaneous bispecific antibody. The study cohort includes 157 patients with relapsed/refractory large B-cell lymphoma (LBCL) who received at least two prior lines of systemic therapy, including 38.9 percent who received prior treatment with chimeric antigen receptor (CAR) T-cell therapy. Based on the topline results, the companies will engage global regulatory authorities to determine next steps.

The topline results from this cohort demonstrated an overall response rate (ORR) of 63.1 percent as confirmed by an independent review committee (IRC), which exceeded the protocol prespecified threshold for efficacy. The observed median duration of response (DOR) was 12 months. The most common treatment-emergent adverse event was cytokine release syndrome (CRS) with 49.7 percent, including 2.5 percent grade 3. The data will be submitted for presentation at a future medical meeting.

Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' broad oncology collaboration. The companies remain committed to evaluating epcoritamab as a monotherapy, and in combination, across lines of therapy, for a variety of hematologic malignancies, including an ongoing phase 3, open-label, randomized trial evaluating epcoritamab as a monotherapy in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) ([NCT: 04628494](#)).

"Together with our partner, AbbVie, we will work with regulatory authorities to determine next steps and continue to evaluate epcoritamab in a variety of clinical trials as a potential treatment option for patients with various hematological malignancies," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We look forward to sharing the findings at a future medical meeting."

LBCL is a fast-growing type of non-Hodgkin's lymphoma (NHL) – a cancer that develops in the lymphatic system – that 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.<sup>1,2,3,4</sup>

"We aim to leverage AbbVie's strong blood cancer expertise to further develop epcoritamab, alongside Genmab, for certain blood cancer patients who have limited treatment options," said Mohamed Zaki, M.D., Ph.D., Vice President and Head, Global Oncology Development, AbbVie.

### About the EPCORE™ NHL-1 Trial

EPCORE™ NHL-1 an open-label, multi-center safety and preliminary efficacy trial of epcoritamab that consists of two parts: a phase 1 first-in-human, dose escalation part; and a phase 2 expansion part. The trial was designed to evaluate subcutaneous epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-NHL, including LBCL and DLBCL. The dose escalation findings, which determined the recommended phase 2 dose RP2D, were published in *The Lancet* in 2021. In the phase 2 expansion part, additional patients are being treated with epcoritamab to further explore the safety and efficacy of epcoritamab in three cohorts of patients with different types of relapsed/refractory B-NHLs who had limited therapeutic options.

The primary endpoint of the expansion part was ORR as assessed by an IRC. Secondary efficacy endpoints included DOR, 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 evaluated as secondary efficacy endpoints.

### 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.<sup>5</sup> 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.<sup>6,7</sup> 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 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](https://www.genmab.com) and follow us on [Twitter.com/Genmab](https://twitter.com/Genmab).

#### **About AbbVie**

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](https://www.abbvie.com). Follow @abbvie on [Twitter](https://twitter.com/abbvie), [Facebook](https://www.facebook.com/abbvie), [Instagram](https://www.instagram.com/abbvie), [YouTube](https://www.youtube.com/abbvie) and [LinkedIn](https://www.linkedin.com/company/abbvie).

#### **Genmab Media Contact:**

Marisol Peron, Senior Vice President, Global Investor Relations & Communications  
T: +1 609 524 0065; E: [mmp@genmab.com](mailto:mmp@genmab.com)

#### **Genmab Investor Relations:**

Andrew Carlsen, Vice President, Head of Investor Relations  
T: +45 3377 9558; E: [acn@genmab.com](mailto:acn@genmab.com)

#### **AbbVie Media Contact:**

U.S. Media  
Ilke Limoncu  
E: [ilke.limoncu@abbvie.com](mailto:ilke.limoncu@abbvie.com)

Global Media  
Mabel Martinez  
E: [mabel.martinez@abbvie.com](mailto:mabel.martinez@abbvie.com)

#### **AbbVie Investor Relations:**

Liz Shea  
E: [liz.shea@abbvie.com](mailto:liz.shea@abbvie.com)

#### **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](https://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](https://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.*

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#### **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. 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 2021 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.*

#### **References**

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<sup>1</sup> "Diffuse Large B-Cell Lymphoma." Lymphoma Research Foundation, <https://www.lymphoma.org/aboutlymphoma/nhi/dlbcl/>; date accessed: 11 February 2022.

<sup>2</sup> "Non-Hodgkin Lymphoma." Lymphoma Research Foundation, <https://www.lymphoma.org/aboutlymphoma/nhl/>; date accessed: 7 April 2022.

<sup>3</sup> Sehn, Salles. "Diffuse Large B-Cell Lymphoma." *New England Journal of Medicine*. 2021;384:842-858. DOI: 10.1056/NEJMra2027612

<sup>4</sup> 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

<sup>5</sup> Engelbert 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.

<sup>6</sup> Rafiq, 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/).

<sup>7</sup> Singh, 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/).

Company Announcement no. 15  
CVR no. 2102 3884  
LEI Code 529900MTJPDPE4MHJ122

Genmab A/S  
Kalvebod Brygge 43  
1560 Copenhagen V  
Denmark

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