

## Genmab Announces Late-Breaking Phase 2 Trial Results of Investigational Epcoritamab (DuoBody®-CD3xCD20) in Relapsed/Refractory Large B-cell Lymphoma (LBCL) Patients Presented at European Hematology Association (EHA) Presidential Symposium

### Media Release

COPENHAGEN, Denmark; June 11, 2022

- Epcoritamab demonstrated clinically meaningful efficacy in challenging to treat, highly refractory LBCL patients, including patients previously treated with chimeric antigen receptor (CAR) T-cell therapy
- Total patient population achieved overall response rate (ORR) of 63 percent and complete response (CR) of 39 percent; CAR T-naïve patients achieved 69 percent ORR and 42 percent CR; patients previously treated with CAR T achieved a 54 percent ORR and 34 percent CR
- Manageable safety profile consistent with previous findings was observed
- Results were reported as part of a late-breaking oral presentation selected for the Presidential Symposium at the EHA Annual Congress

**[Genmab A/S](#) (Nasdaq: **GMAB**) announced today primary results from the large B-cell lymphoma (LBCL) expansion cohort in the **EPCORE™ NHL-1** phase 2 clinical trial evaluating subcutaneous epcoritamab (DuoBody®-CD3xCD20), an investigational bispecific antibody. In the study, treatment with epcoritamab demonstrated deep and durable responses with an overall response rate (ORR) of 63 percent and a complete response rate (CR) of 39 percent in patients who had previously received at least two prior lines of systemic anti-lymphoma therapy. Additionally, patients naïve to treatment with chimeric antigen receptor (CAR) T-cell therapy achieved 69 percent ORR and 42 percent CR and patients previously treated with CAR T achieved a 54 percent ORR and 34 percent CR. Data were presented in a late-breaking oral presentation as a part of the Presidential Symposium at the 27<sup>th</sup> Annual Meeting of the European Hematology Association (EHA2022) in Vienna, Austria (Abstract #LB2364).**

“Large B-cell lymphoma is a fast-growing, difficult to treat type of aggressive non-Hodgkin’s lymphoma. Some treatment approaches like chemotherapy and immunotherapy have been in place for decades and newer treatments like CAR T-cell therapies involve multiple steps before a patient can begin treatment, so there is still a need for additional treatment options,” said Professor Catherine Thieblemont, Head of the Hemato-Oncology Department at Hôpital Saint-Louis, Paris, France. “The data presented today suggest that epcoritamab has the potential to provide patients living with relapsed/refractory LBCL an accessible, effective treatment with a safety profile that may fulfill an unmet need.”

The study cohort, which included 157 relapsed/refractory LBCL patients, previously treated with a median of three lines of prior therapy, demonstrated an overall response rate (ORR) of 63 percent and a complete response rate (CR) of 39 percent. Baseline characteristics included 61 percent of patients who were refractory to primary treatment, 20 percent who had prior autologous stem cell transplantation (ASCT), and 39 percent who were treated with CAR T-cell therapy (75 percent of those refractory to CAR T). Patients enrolled in the study who were naïve to CAR T therapy achieved a 69 percent ORR and a 42 percent CR and patients who received prior CAR T-cell treatment achieved a 54 percent ORR and a 34 percent CR. After a median follow up of 10.7 months, the median duration of response (mDOR) was estimated to be 12 months, while the mDOR among patients achieving a CR was not reached, with 89 percent still in CR at nine months. Topline results from this study were previously [announced](#) in April 2022.

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“These latest data are promising because they suggest that treatment with epcoritamab may benefit patients with this fast-growing, aggressive and difficult to treat type of non-Hodgkin’s lymphoma who are in need of new therapeutic advances,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “We are encouraged by the potential of epcoritamab and look forward to continuing to advance our robust clinical development program with our partner, AbbVie.”

The safety profile of epcoritamab was manageable and consistent with previous findings. The majority of treatment-emergent AEs (TEAEs) occurred during the first 12 weeks of treatment and resolved. The most common TEAEs of any grade (greater than or equal to 15 percent) included cytokine release syndrome (CRS) (49.7 percent), pyrexia (23.6 percent), fatigue (22.9 percent), neutropenia (21.7 percent), diarrhea (20.4 percent), injection site reaction (19.7%), nausea (19.7%), and anemia (17.8%). The most common Grade 3 or 4 treatment-emergent adverse events (greater than or equal to 5 percent) included neutropenia (14.6 percent), anemia (10.2 percent), neutrophil count decrease (6.4 percent), and thrombocytopenia (5.7 percent). The observed Grade 3 CRS was low (2.5 percent). No Grade 4/5 CRS was observed.

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 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 – 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>

### About the EPCORE™ NHL-1 Trial

EPCORE™ NHL-1 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. The dose escalation findings, 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 three cohorts of patients with different types of relapsed/refractory B-NHLs who had limited therapeutic options.

The primary endpoint of the phase 2 expansion part was ORR as assessed by an IRC. Secondary efficacy endpoints included duration of response, complete response rate, 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 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.<sup>5</sup> Epcoritamab was developed with selective, silencing mutations that may limit systemic, non-specific activity. CD20 is expressed on B-cells and a clinically validated therapeutic target in many B-cell malignancies, including diffuse large B-cell lymphoma,

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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](http://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](http://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](http://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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<sup>1</sup> "Diffuse Large B-Cell Lymphoma." Lymphoma Research Foundation, <https://www.lymphoma.org/aboutlymphoma/nhl/dlbcl/>. Date accessed: 7 June 2022.

<sup>2</sup> "Non-Hodgkin Lymphoma." Lymphoma Research Foundation, <https://lymphoma.org/aboutlymphoma/nhl/>. Date accessed: 7 June 2022.

<sup>3</sup> Sehn, Salles. "Diffuse Large B-Cell Lymphoma." N Engl J Med. 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> 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

<sup>6</sup> 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

<sup>7</sup> 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