New Pivotal Data for Bispecific Antibody Epcoritamab (DuoBody® CD3xCD20) Demonstrates High Overall and Complete Responses in Patients with Hard-To-Treat Relapsed/Refractory Follicular Lymphoma (FL)

Media Release

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- **Data from the pivotal phase 1/2 EPCORE™ NHL-1 study showed 82 percent overall response rate (ORR), 63 percent complete response (CR) and 67 percent minimal residual disease (MRD) negativity in patients with relapsed/refractory (R/R) follicular lymphoma (FL) treated with subcutaneous epcoritamab**
- **Results presented at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition include data from an optimized step-up dosing schedule for FL patients showing meaningful reduction in risk and severity of cytokine release syndrome (CRS)**
- **Follicular lymphoma is the second most common form of non-Hodgkin's lymphoma, is considered incurable and can be difficult to treat in the R/R setting**

Genmab A/S (Nasdaq: GMAB) and AbbVie (NYSE: ABBV) today announced new data from the ongoing phase 1/2 EPCORE™ NHL-1 clinical trial investigating epcoritamab (DuoBody® CD3xCD20), a T-cell engaging bispecific antibody administered subcutaneously, demonstrated an overall response rate (ORR) of 82 percent, a complete response (CR) rate of 63 percent and minimal residual disease (MRD) negativity rate of 67 percent in patients with relapsed/refractory (R/R) follicular lymphoma (FL). The presentation included data from an optimized step-up dosing schedule for FL patients showing a reduction in risk and severity of Grade 2+ cytokine release syndrome (CRS), a common side effect of T-cell engaging cancer treatments. These results were presented today at the 2023 65th Annual Meeting and Exposition of the American Society of Hematology (ASH), being held in San Diego, California, December 9-12, 2023 (Abstract #1655).

"Despite treatment advances for patients with follicular lymphoma whose disease has unfortunately progressed, treating relapsed or refractory follicular lymphoma remains highly challenging, particularly in the third-line plus setting," said Catherine Thieblemont, M.D., Ph.D., head of the hemato-oncology department, Paris University, Hôpital Saint-Louis Assistance-Publique-Hopitaux de Paris (APHP) in Paris. "The patients in this trial represent a historically difficult-to-treat patient population. The data presented today are especially notable because they demonstrated high overall and complete response rates for this investigational follicular lymphoma therapy and a preview for its potential as an alternative treatment option."

Overall results from the pivotal cohort of 128 adult patients showed that:

- At a median follow-up of 17.4 months, the study's primary endpoint ORR was 82 percent, which exceeded the protocol defined threshold for efficacy, with a CR rate of 63 percent, and 67 percent MRD negativity.
- The median time to response was 1.4 months and median time to CR was 1.5 months.
- Median progression-free survival (PFS) for patients who achieved a CR was not reached nor was the median duration of response, duration of CR, MRD negativity and overall survival.
- An estimated 85 percent and 74 percent of patients who experienced a CR remained in response at 12 and 18 months, respectively.

Among prespecified subgroups, ORR and CR rates were generally consistent with the overall patient population. Notably, high-risk patients who were refractory to both anti-CD20 therapy and an alkylating agent achieved a 76 percent ORR and 56 percent CR; patients who were refractory to last prior treatment

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achieved a 74 percent ORR and 51 percent CR rate; and patients whose disease progressed within two years of first-line immunochemotherapy (POD24) achieved an 80 percent ORR and 61 percent CR.

Safety findings were consistent with previous epcoritamab trials, and epcoritamab was generally well tolerated. Following an optimized step-up dose regimen for FL patients (n=50) to reduce the risk and severity of CRS, 40 percent of patients experienced Grade 1 CRS and 8 percent experienced Grade 2 (no Grade 3 or higher CRS were reported) and no Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) was reported. This data may support outpatient administration. Additional common treatment-emergent adverse events (TEAEs) from the pivotal cohort (>20 percent) were injection-site reaction (57 percent), COVID-19 (40 percent), fatigue (30 percent), neutropenia (29 percent), diarrhea (27 percent) and pyrexia (25 percent). TEAEs leading to treatment discontinuation occurred in 19 percent of patients, and Grade 5 TEAEs occurred in 13 patients (10 percent).

“Follicular lymphoma patients who have experienced a relapse following heavy pre-treatment, or whose disease is not responding to available therapies, are considered high risk and are in need of alternative therapeutic options,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “The data presented at ASH reinforce what we have seen from our epcoritamab research and believe that this investigational bispecific antibody could potentially represent an important treatment option for patients living with relapsed or refractory follicular lymphoma. Along with our partner AbbVie, we look forward to progressing epcoritamab in clinical trials and discussing the results with regulatory authorities and remain committed to developing epcoritamab as a potential future core therapy for B-cell malignancies.”

About the Phase 1/2 EPCORE™ NHL-1 Trial
EPCORE™ NHL-1 an open-label, multi-center safety and preliminary efficacy trial of epcoritamab that consists of three parts: a phase 1 first-in-human, dose escalation part; a phase 2a expansion part; and a phase 2a dose optimization part. The trial was designed to evaluate subcutaneous epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-cell non-Hodgkin’s lymphoma (B-NHL), including FL. In the phase 2a expansion part, additional patients were enrolled to further explore the safety and efficacy of epcoritamab in three cohorts of patients with different types of relapsed/refractory B-NHLs who have limited therapeutic options. The dose optimization part evaluates the potential for alternative step-up dosing regimens to help further minimize Grade 2 cytokine release syndrome (CRS) and mitigate Grade ≥3 CRS. 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 also evaluated as secondary efficacy endpoints.

About Follicular Lymphoma (FL)
FL is typically an indolent (or slow growing) form of non-Hodgkin’s lymphoma (NHL) that arises from B-lymphocytes.[i] FL is the second most common form of NHL overall, accounting for 20-30 percent of all NHL cases, and represents 10-20 percent of all lymphomas in the western world.[i,ii,iii] Although FL is an indolent lymphoma, it is considered incurable with conventional therapy[iv,v] and patients who achieve remission also often experience relapse.[vi]

About Epcoritamab
Epcoritamab is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody® technology and administered subcutaneously. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response toward target cell types. Epcoritamab is designed to

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simultaneously bind to CD3 on T cells and CD20 on B cells and induces T-cell-mediated killing of CD20+ cells.[vii]

Epcoritamab (approved under the brand name EPKINLY® in the U.S. and Japan, and TEPKINLY® in the EU) has received regulatory approval in certain lymphoma indications in several territories. Use of epcoritamab in FL is not approved in any country, including the U.S. and the EU. 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.

Genmab and AbbVie continue to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes three ongoing phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL (NCT: 04628494) compared to investigators choice chemotherapy, a phase 3 trial evaluating epcoritamab in combination with R-CHOP in adult participants with newly diagnosed DLBCL (NCT: 05578976), and a phase 3, open-label clinical trial evaluating epcoritamab in combination with rituximab and lenalidomide in patients with R/R FL (NCT: 05409066). Epcoritamab is not approved to treat newly diagnosed patients with DLBCL or FL. The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit clinicaltrials.gov for more information.

About Genmab
Genmab is an international biotechnology company with a core purpose guiding its unstoppable team to strive towards improving the lives of patients through innovative and differentiated antibody therapeutics. For more than 20 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational research and data sciences, which has resulted in a proprietary pipeline including bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. To help develop and deliver novel antibody therapies to patients, Genmab has formed 20+ strategic partnerships with biotechnology and pharmaceutical companies. By 2030, Genmab's vision is to transform the lives of people with cancer and other serious diseases with Knock-Your-Socks-Off (KYSO™) antibody medicines.

Established in 1999, 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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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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[i] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed June 2023.
[ii] Ma S. Risk factors of follicular lymphoma. Expert Opin Med Diagn. 2012;6:323–33. doi: 10.1517/17530059.2012.686996.
[iii] Luminari S, Bellei M, Biasoli I, Federico M. Follicular lymphoma—treatment and prognostic factors. Rev Bras Hematol Hemoter. 2012;34:54–9. doi: 10.5581/1516-8484.20120015.
[iv] Link BK, et al. Second-Line and Subsequent Therapy and Outcomes for Follicular Lymphoma in the United States: Data From the Observational National LymphoCare Study. Br J Haematol 2019;184(4):660-663.
[v] Ren J, et al. Economic Burden and Treatment Patterns for Patients With Diffuse Large B-Cell Lymphoma and Follicular Lymphoma in the USA. J Comp Eff Res 2019;8(6):393-402.
[vi] Lymphoma Research Foundation official website. https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/follicular-lymphoma/relapsedfl/. Accessed November 2023.
[vii] Engelberts PJ, Hiemstra IH, de Jong B, 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.