Genmab and AbbVie Announce Positive Topline Results from Phase 1/2 EPCORE™ NHL-1 Trial Evaluating Epcoritamab (DuoBody® CD3xCD20) in Patients with Relapsed/Refractory Follicular Lymphoma (FL)

Company Announcement

- **Based on the topline results from the EPCORE™ NHL-1 clinical trial, Genmab and AbbVie will engage with global regulatory authorities to discuss next steps**
- **Data from the clinical trial will be presented at a future medical meeting**
- **Follicular Lymphoma is a common form of non-Hodgkin's lymphoma (NHL) and currently has limited treatment options, particularly in the relapsed/refractory setting**

COPENHAGEN, Denmark; June 28, 2023 – Genmab A/S (Nasdaq: GMAB) and AbbVie (NYSE: ABBV) today announced topline results from the follicular lymphoma (FL) cohort of the phase 1/2 EPCORE™ NHL-1 clinical trial evaluating epcoritamab (DuoBody® CD3xCD20), an investigational T-cell engaging bispecific antibody administered subcutaneously. The study cohort includes 128 adult patients with relapsed/refractory follicular lymphoma (FL) who received at least two prior lines of systemic therapy. 70.3 percent of patients were double refractory to an anti-CD20 monoclonal antibody and an alkylating agent. Based on the topline results, the companies will engage with global regulatory authorities to determine next steps. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration.

The topline results from this cohort showed an overall response rate (ORR) of 82 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 not reached. No new safety signals were observed with epcoritamab in this study at the time of analysis. The most common treatment-emergent adverse event was cytokine release syndrome (CRS) with 66.4 percent (1.6 percent grade >2). Aligned with the U.S. Food and Drug Administration's (FDA) Project Optimus, the optimization part of the trial is continuing to evaluate alternative step-up dosing regimens to mitigate the risk of CRS; preliminary data on the initial patients enrolled indicate a clinically meaningful improvement in CRS rate. The results from this cohort, along with the results from the optimization part of the trial, will be submitted for presentation at an upcoming medical congress.

"These topline results are encouraging for relapsed or refractory follicular lymphoma patients who are in need of new therapeutic options," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "With our partner AbbVie, we are committed to evaluating epcoritamab as a potential core therapy across B-cell malignancies. We look forward to sharing the full results from this study cohort at an upcoming medical congress and discussing the results with global regulatory authorities."

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 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-cell non-Hodgkin's lymphoma (B-NHL), including FL. In the phase 2 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 optimization part evaluates the potential for alternative step-up dosing regimens to further minimize grade 2 CRS and mitigate the risk of 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 evaluated as secondary efficacy endpoints.

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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.[ii,iii] Although FL is an indolent lymphoma, it is considered incurable with conventional therapy.[iv,v]

About Epcoritamab
Epcoritamab is an investigational 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 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.[vi]

Epcoritamab-bysp (EPKINLY™) was recently approved in the United States and is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In October 2022, a Marketing Authorization Application was submitted for epcoritamab for the treatment of patients with R/R DLBCL after two or more lines of systemic therapy, which was validated by the European Medicines Agency. Additionally, in December 2022, a Japan new drug application was submitted to the Ministry of Health, Labor and Welfare of Japan for epcoritamab for the treatment of patients with R/R LBCL after two or more lines of systemic therapy. Epcoritamab is not approved in the European Union and Japan. The companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. AbbVie will continue to pursue regulatory submissions for epcoritamab across international markets excluding the U.S. and Japan throughout the year.

Genmab and AbbVie are continuing to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes an ongoing phase 3, open-label, randomized trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL (NCT: 04628494), an ongoing phase 3, open-label, randomized trial evaluating epcoritamab in combination in adult participants with newly diagnosed DLBCL (NCT: 05578976), and a phase 3, open-label clinical trial evaluating epcoritamab in combination in patients with R/R follicular lymphoma (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.

EPKINLY™ (epcoritamab-bysp) U.S. IMPORTANT SAFETY INFORMATION

Important Warnings—EPKINLY can cause serious side effects, including:

- **Cytokine Release Syndrome (CRS).** CRS is common during treatment with EPKINLY and can be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop symptoms of CRS, including fever of 100.4°F (38°C) or higher, dizziness or lightheadedness, trouble breathing, chills, fast heartbeat, feeling anxious, headache, confusion, shaking (tremors), or problems with balance and movement, such as trouble walking.

Due to the risk of CRS, you will receive EPKINLY on a "step-up" dosing schedule. The step-up dosing schedule is when you receive smaller "step-up" doses of EPKINLY on day 1 and day 8 of your first cycle of treatment (cycle 1). You will receive your first full dose of EPKINLY on day 15 of cycle 1. If your dose of EPKINLY is delayed for any reason, you may need to repeat the step-up dosing schedule. Before each dose in cycle 1, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicine to help reduce your risk of CRS with future cycles.

- **Neurologic problems.** EPKINLY can cause serious neurologic problems that can be life-threatening and lead to death. Neurologic problems may happen days or weeks after you receive EPKINLY. Your healthcare provider may refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any symptoms of neurologic problems, including trouble speaking or writing, confusion and disorientation, drowsiness, tiredness or lack of energy, muscle weakness, shaking (tremors), seizures, or memory loss.

Due to the risk of CRS and neurologic problems, you should be hospitalized for 24 hours after receiving your first full dose of EPKINLY on day 15 of cycle 1. Your healthcare provider will monitor you for symptoms of CRS and neurologic problems during treatment with EPKINLY, as well as other side effects, and treat you if needed. Your healthcare provider may temporarily stop or completely stop your treatment with EPKINLY if you develop CRS, neurologic problems, or any other side effects that are severe.

Do not drive or use heavy or potentially dangerous machinery if you develop dizziness, confusion, tremors, drowsiness, or any other symptoms that impair consciousness until your symptoms go away. These may be symptoms of CRS or neurologic problems.

EPKINLY can also cause other serious side effects, including:

- **Infections.** EPKINLY can cause serious infections that may lead to death. Your healthcare provider will check you for symptoms of infection before and during treatment. Tell your healthcare provider right away if you develop any symptoms of infection during treatment, including fever of 100.4°F (38°C) or higher, cough, chest pain, tiredness, shortness of breath, painful rash, sore throat, pain during urination, or feeling weak or generally unwell.
- **Low blood cell counts.** Low blood cell counts are common during treatment with EPKINLY and can be serious or severe. Your healthcare provider will check your blood cell counts during treatment. EPKINLY may cause low blood cell counts, including **low white blood cell counts (neutropenia)**, which can increase your risk for infection; **low red blood cell counts (anemia)**, which can cause tiredness and shortness of breath; and **low platelet counts (thrombocytopenia)**, which can cause bruising or bleeding problems.

Your healthcare provider may temporarily stop or completely stop treatment with EPKINLY if you develop certain side effects.

Before you receive EPKINLY, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection.

- are pregnant or plan to become pregnant. EPKINLY may harm your unborn baby**. Females who are able to become pregnant:** Your healthcare provider should do a pregnancy test before you start treatment with EPKINLY. You should use effective birth control (contraception) during treatment and for 4 months after your last dose of EPKINLY. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with EPKINLY.
- are breastfeeding or plan to breastfeed. It is not known if EPKINLY passes into your breast milk. Do not breastfeed during treatment with EPKINLY and for 4 months after your last dose of EPKINLY.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of EPKINLY include CRS, tiredness, muscle and bone pain, injection site reactions, fever, stomach-area (abdominal) pain, nausea, and diarrhea.

These are not all the possible side effects of EPKINLY. Call your doctor for medical advice about side effects.

You are encouraged to report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to Genmab US, Inc. at 1-855-4GENMAB (1-855-443-6622).

Please see the **Full Prescribing Information** and **Medication Guide**, including Important Warnings.

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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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,

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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.

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[i] Lymphoma Research Foundation official website. https://lymphoma.org/aboutlymphoma/nhl/fl/. Accessed June 2023.
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[vi] 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