Investigational Epcoritamab (DuoBody® CD3xCD20) Combination Therapy Demonstrates High Response Rates in Clinical Trial of Patients With Relapsed or Refractory (R/R) Follicular Lymphoma (FL)

Media Release

COPENHAGEN, Denmark; December 7, 2024

- **Results show 96 percent overall response rate (ORR), 87 percent complete response (CR), and 80 percent 21-month progression-free survival (PFS) in patients with relapsed or refractory (R/R) follicular lymphoma (FL) following treatment with epcoritamab plus lenalidomide + rituximab (R^2)**
- **Long-term follow-up results demonstrated strong and durable efficacy, with an estimated two-year overall survival (OS) rate of 90 percent**
- **Results follow recent breakthrough therapy designation (BTD) granted by U.S. Food and Drug Administration (FDA) and support ongoing Phase 3 EPCORE® FL-1 trial evaluating epcoritamab + R^2 in patients with R/R FL**

Genmab A/S (Nasdaq: GMAB) today announced new results from the Phase 1b/2 EPCORE® NHL-2 trial evaluating fixed-duration epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, plus lenalidomide + rituximab (R^2) in adult patients with relapsed or refractory (R/R) follicular lymphoma (FL). The results demonstrated an overall response rate (ORR) of 96 percent and a complete response (CR) rate of 87 percent among 111 patients after a median follow-up of two years. Additionally, the study showed an estimated 21-month progression-free survival (PFS) rate of 80 percent and a two-year overall survival (OS) rate of 90 percent. The data (Abstract #342) were shared today during an oral presentation at the 66th Annual Meeting and Exposition of the American Society of Hematology (ASH).

“Follicular lymphoma is incurable in most patients, and patients living with relapsed or refractory follicular lymphoma, particularly those with high-risk features, are in need of additional therapeutic options,” said Lorenzo Falchi, MD, Lymphoma Specialist, Department of Medicine, Memorial Sloan Kettering Cancer Center.[i] “The durable responses seen in the EPCORE NHL-2 trial are encouraging and support the ongoing investigation of epcoritamab in combination with the standard regimen of rituximab plus lenalidomide.”

Additional data from the study showed an estimated 89 percent of complete responders to the combination therapy remained in CR at 18 months (duration of CR; DoCR).

With the majority of patients being enrolled and treated during the global COVID-19 pandemic, COVID-19 was reported in 57 percent of patients and led to epcoritamab discontinuation in 13 percent of patients. Five cases of COVID-19 led to fatal treatment-emergent adverse events (TEAEs; COVID-19, n=3; COVID-19 pneumonia, n=2). The other most common TEAEs were neutropenia (62 percent) and cytokine release syndrome (CRS; 51 percent). CRS events with the 2-step step-up dose regimen were mostly low grade (38 percent Grade 1, 12 percent Grade 2, 2 percent Grade 3) and primarily occurred following the first full dose. All CRS cases resolved. One case of immune effector cell-associated neurotoxicity syndrome (ICANS) was reported (Grade 1). The CRS and ICANS cases did not lead to treatment discontinuation.

“The long-term results for epcoritamab combination therapy presented at ASH are very encouraging for patients facing the challenges of relapsed or refractory follicular lymphoma,” said Dr. Judith Klimovsky, Executive Vice President & Chief Development Officer, Genmab. “These data reinforce the potential of epcoritamab in follicular lymphoma across treatment lines and support our goal to develop epcoritamab as a potential core therapy for the treatment of B-cell malignancies, both as a monotherapy and with

different combinations of standards of care across different lines of therapy and patient populations. We look forward to further evaluating this combination in the ongoing Phase 3 EPCORE FL-1 trial."

The U.S. Food and Drug Administration (FDA) recently granted breakthrough therapy designation (BTD) for epcoritamab plus R^2 for the treatment of adult patients with R/R FL who have received at least one prior line of therapy. Epcoritamab in combination with R^2 is being studied further in the ongoing, randomized, Phase 3 EPCORE FL-1 trial (NCT05409066).

Use of epcoritamab + R^2 in R/R FL is not approved in the U.S. or in the EU or in any other territory. The safety and efficacy of epcoritamab for use as a combination therapy in FL have not been established.

About Follicular Lymphoma (FL)
FL is typically an indolent (or slow-growing) form of non-Hodgkin's lymphoma (NHL) that arises from B-lymphocytes and is the second most common form of NHL accounting for 20-30 percent of all cases.[ii] About 15,000 people develop FL each year in the U.S.[iii] and it is considered incurable with current standard of care therapies.[iv] Patients often relapse and, with each relapse the remission and time to next treatment is shorter.[v] Over time, transformation to diffuse large B-cell lymphoma (DLBCL), an aggressive form of NHL associated with poor survival outcomes, can occur in more than 25 percent of FL patients.[vi]

About the EPCORE® NHL-2 Trial
EPCORE® NHL-2 is a Phase 1b/2 open-label interventional trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics/biomarkers, immunogenicity, and preliminary efficacy of epcoritamab as a monotherapy and in combination with other standard of care agents in patients with B-cell non-Hodgkin's lymphoma (B-NHL). The trial consists of two parts: Part 1 (Dose Escalation) and Part 2 (Dose Expansion). The primary objective of Part 1 is safety, and the primary goal of Part 2 is preliminary efficacy. Arm 2 of the trial is epcoritamab + rituximab and lenalidomide (R^2) in participants with relapsed/refractory (R/R) follicular lymphoma (FL). More information on this trial can be found at https://www.clinicaltrials.gov/ (NCT: 04663347).

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 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. 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. Both companies will pursue additional international regulatory approvals for the investigational R/R FL indication and additional approvals for the R/R DLBCL indication.

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 five ongoing Phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL compared to investigators choice chemotherapy (NCT04628494), a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL (NCT05578976), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R^2) in patients with R/R FL (NCT05409066), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R^2)

compared to chemoimmunotherapy in patients with previously untreated FL (NCT06191744), and a trial evaluating epcoritamab in combination with lenalidomide compared to chemotherapy infusion in patients with R/R DLBCL (NCT06508658). The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit www.clinicaltrials.gov for more information.

About Genmab
Genmab is an international biotechnology company with a core purpose of guiding its unstoppable team to strive toward improving the lives of patients with innovative and differentiated antibody therapeutics. For 25 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational, quantitative and data sciences, resulting in a proprietary pipeline including bispecific T-cell engagers, antibody-drug conjugates, next-generation immune checkpoint modulators and effector function-enhanced antibodies. 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 international presence across North America, Europe and Asia Pacific. For more information, please visit Genmab.com and follow us on LinkedIn and X.

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[i] Dr. Falchi has financial interests related to Genmab and AbbVie.
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