Genmab Showcases Data From Robust Development Program Evaluating Epcoritamab (DuoBody®-CD3xCD20) in Patients Across a Broad Range of B-Cell Lymphomas at the 64th Annual ASH Meeting

Media Release

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- **Epcoritamab featured in multiple data disclosures, including four oral presentations**
- **Results presented from the phase 1b/2 EPCORE™ NHL-2 trial of epcoritamab combined with standard salvage therapy in patients with transplant eligible relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL)**
- **Additional results also presented from the phase 1b/2 EPCORE NHL-2 trial evaluating epcoritamab combined with existing therapies in patients with R/R follicular lymphoma (FL) and previously untreated FL**
- **Results presented from phase 1b/2 EPCORE CLL-1 trial evaluating epcoritamab in patients with Richter's Syndrome (RS)**
- **Additional results also presented from the phase 1/2 EPCORE NHL-1 trial, evaluating epcoritamab in patients with R/R large B-cell lymphoma (LBCL)**

Genmab A/S (Nasdaq: GMAB) today announced the results from multiple clinical trials evaluating epcoritamab (DuoBody®-CD3xCD20), an investigational subcutaneous bispecific antibody, alone or in combination with other therapies for the treatment of patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), R/R follicular lymphoma (FL), previously untreated FL, and Richter's Syndrome (RS). These data, along with additional results from the phase 1/2 EPCORE NHL-1 clinical trial, evaluating the safety and efficacy of epcoritamab in patients with R/R large B-cell lymphoma (LBCL), are being presented at the 64th Annual Meeting and Exposition of the American Society of Hematology (ASH), being held in New Orleans, Louisiana, and virtually, December 10-13, 2022.

"The breadth of clinical data for epcoritamab presented at ASH demonstrates Genmab's commitment to addressing treatment needs for people living with a variety of B-cell lymphomas," said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. "Together with AbbVie, we continue to evaluate epcoritamab in various treatment settings and patient populations to unlock its potential to become a core therapy for B-cell malignancies."

Notably, results from the phase 1b/2 EPCORE NHL-2 arm (Abstract #443) evaluating 27 patients with R/R DLBCL who were eligible for autologous stem cell transplant, showed an 85 percent (23/27) overall response rate (ORR) and a 67 percent (18/27) complete metabolic response (CMR) rate, following treatment with the combination of subcutaneous epcoritamab plus standard rituximab, dexamethasone, cytarabine, and oxaliplatin or carboplatin (R-DHAX/C) salvage therapy. The most common treatment-emergent adverse events (TEAEs) of any grade were thrombocytopenia (69 percent), anemia (51 percent), neutropenia (44 percent), cytokine release syndrome (CRS) (41 percent), nausea (31 percent), fatigue (28 percent), constipation, diarrhea, headache, pyrexia (all at 24 percent), and increased aspartate aminotransferase (AST) (21 percent). These results were highlighted during an oral presentation on Sunday, December 11, 2022, at 10:30 a.m. CST.

Results from two additional arms of the EPCORE NHL-2 study, evaluating subcutaneous epcoritamab in combination with rituximab and lenalidomide, one arm in patients with R/R FL and the other arm in previously untreated FL, will be presented during an oral session on Sunday, December 11, 2022, beginning at 4:30 p.m. CST.

In the R/R FL arm (Abstract #609), 95 percent (63/66) of efficacy evaluable patients treated with subcutaneous epcoritamab in combination with rituximab and lenalidomide achieved an overall response. Among these patients, 80 percent (53/66) achieved a CMR, and 15 percent (10/66) achieved a partial metabolic response (PMR). The majority of patients achieved a response at the first tumor response assessment and most continued to respond through the latest assessment at the time of data collection. The most common TEAEs of any grade were neutropenia (47 percent), CRS (43 percent), injection-site reactions (32 percent), fatigue (31 percent), constipation, COVID-19, pyrexia (all at 25 percent), and infusion-related reaction (21 percent).

In the previously untreated FL patient arm (Abstract #611), 94 percent (34/36) of efficacy evaluable patients who received subcutaneous epcoritamab in combination with rituximab and lenalidomide achieved an overall response, including 86 percent (31/36) achieving a CMR as their best overall response. The most common TEAEs of any grade were CRS (54 percent), neutropenia (47 percent), pyrexia (44 percent), fatigue (37 percent), injection site reaction (37 percent), headache (34 percent), COVID-19 (33 percent), diarrhea (32 percent), constipation (29 percent), rash (27 percent), increased alanine aminotransferase (ALT) (22 percent), and vomiting (22 percent).

Preliminary results from the phase 1b/2 open-label, multi-center safety and efficacy EPCORE CLL-1 trial (Abstract #348) showed that treatment with investigational subcutaneous epcoritamab monotherapy had promising antitumor activity in 10 patients with Richter's Syndrome, with a 60 percent ORR and a 50 percent CMR rate. Most responses were observed by the first assessment at week six. The most common related TEAEs of any grade percent were CRS (90 percent), anemia (50 percent), neutropenia (50 percent), injection-site reaction (40 percent), thrombocytopenia (40 percent), and hypophosphatemia, hypokalemia, hyperglycemia, COVID-19, diarrhea, fatigue, and nausea (all at 30 percent). These results were highlighted during an oral session on Saturday, December 10, 2022, at 5:15 p.m. CST.

About Diffuse Large B-cell Lymphoma (DLBCL)
Diffuse large B-cell lymphoma (DLBCL) is a fast-growing type of non-Hodgkin's lymphoma (NHL) that affects B-cell lymphocytes, a type of white blood cell.[1] It is the most common type of NHL worldwide and accounts for approximately 30 percent of all NHL cases.[1] DLBCL can arise in lymph nodes, as well as in organs outside of the lymphatic system.[1] The disease occurs more commonly in the elderly and is slightly more prevalent in men.[1]

About Follicular Lymphoma (FL)
Approximately 2.7 per 100,000 people in the U.S. are newly diagnosed with FL every year and the median age of patients at diagnoses with FL is 63.[2,3,4] FL is typically an indolent (or slow growing) form of non-Hodgkin's lymphoma (NHL) that arises from B-lymphocytes.[5] Although FL is an indolent lymphoma, it is considered incurable with conventional therapy.[6,7]

About Richter's Syndrome (RS)
RS, also known as Richter's Transformation, is defined as the transformation of chronic lymphocytic leukemia (CLL) into an aggressive lymphoma, most commonly diffuse large B-cell lymphoma (DLBCL).[8,9] RS occurs in approximately 2 to 10 percent of CLL patients during the course of their disease.[8]

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 cells. 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.[10] CD20 is expressed on B-cells and a clinically validated therapeutic target in many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.[11,12]

Genmab recently announced that the Biologics License Application (BLA) for epcoritamab for the treatment or R/R LBCL was accepted for Priority Review by the U.S. Food and Drug Administration (FDA), with an FDA action date of May 21, 2023. Additionally, the European Medicines Agency (EMA) recently validated the Marketing Authorization Application (MAA) for epcoritamab for the treatment of adult patients with R/R DLBCL after two or more lines of systemic therapy.

Epcoritamab is being co-developed by AbbVie and Genmab 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. The companies are committed to evaluating 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 relapsed/refractory diffuse large B-cell lymphoma (NCT: 04628494) and a Phase 3, open-label clinical trial evaluating epcoritamab in combination in patients with relapsed/refractory follicular lymphoma (NCT: 05409066).

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 and follow us on Twitter.com/Genmab.

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