

Genmab Announces Multiple Abstracts to be Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) Congress

Media Release

COPENHAGEN, Denmark; May 25, 2023

- Oral presentations will highlight epcoritamab-bysp in combination with rituximab-lenalidomide (R2) in high-risk follicular lymphoma
- Poster presentations will highlight epcoritamab in lymphoma across multiple lines of therapy and histologies where high unmet needs exist

Genmab A/S (Nasdaq: GMAB) announced today that multiple abstracts evaluating epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago, IL and virtually, June 2-6, 2023, and at the 2023 European Hematology Association (EHA) Congress, being held in Frankfurt, Germany and virtually, June 8-11, 2023.

Presentations will include data from clinical trials evaluating the efficacy of epcoritamab in combination with standard-of-care therapies for the treatment of various types of B-cell non-Hodgkin lymphoma (NHL), including first-line, high-risk diffuse large B-cell lymphoma (DLBCL), relapsed or refractory large B-cell lymphoma (LBCL), and relapsed or refractory follicular lymphoma (FL). The safety and efficacy of epcoritamab has not been established for these investigational uses.

All abstracts accepted for presentation have been published and may be accessed online via the [ASCO Meeting Library](#) and [EHA Open Access Library](#).

“The data being presented this year at ASCO and EHA demonstrate Genmab’s significant progress towards our mission to develop targeted antibody therapies with the goal of improving the lives of people impacted by hematologic malignancies,” said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. “Together with AbbVie, we are committed to evaluating epcoritamab as a potential therapy for a variety of B-cell lymphomas through a robust clinical development program.”

Genmab has also submitted abstracts evaluating epcoritamab, for potential presentation at the International Conference on Malignant Lymphoma, taking place June 13-17, 2023, in Lugano, Switzerland.

Abstracts accepted for presentation at ASCO include:

Epcoritamab:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
7506	Epcoritamab + R2 regimen and responses in high-risk follicular lymphoma, regardless of POD24 status. R. W. Merryman, et al.	Oral	Tuesday, June 6, 2023, 11:45 AM CDT
7525	Effect of follow-up time on the ability of subcutaneous epcoritamab to induce deep and durable complete remissions in patients with relapsed/refractory large B-cell lymphoma: Updated results from the pivotal EPCORE™ NHL-1 trial; Y. Karimi, et al.	Poster	Monday, June 5, 2023, 08:00 AM - 11:00 AM CDT

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7519	Metabolic response rates of epcoritamab + R-CHOP in patients with previously untreated (1L) high-risk diffuse large B-cell lymphoma, including double-hit/triple-hit lymphoma: Updated EPCORE NHL-2 data; L. Falchi, et al.	Poster Discussion	Monday, June 5, 2023, 1:15 PM CDT
7592	Phase 3 trial of subcutaneous epcoritamab + R-CHOP versus R-CHOP in patients (pts) with newly diagnosed diffuse large B-cell lymphoma (DLBCL): EPCORE DLBCL-2. L. Sehn, et al.	Poster	Monday, June 5, 2023, 08:00 AM - 11:00 AM CDT
e18919	Practice efficiency of treatment with epcoritamab versus glofitamab in relapsed/refractory diffuse large B-cell lymphoma. D. Huang, et al.	Publication	NA

Real-World Evidence:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
7552	Real-world outcomes with novel therapies in R/R DLBCL. J. Crombie, et al.	Poster	Monday, June 5, 2023, 08:00 AM - 11:00 AM CDT
e19530	Racial and ethnic representation in large B-cell lymphoma trials and real-world databases. J. Munoz, et al.	Publication	NA

Abstracts accepted for presentation at EHA include:

Epcoritamab:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
S222	Epcoritamab with rituximab + lenalidomide (R2) provides durable responses in patients with high-risk follicular lymphoma, regardless of POD24 status. A. Sureda, et al.	Oral	Friday, June 9, 2023, 15:15 PM – 15:30 PM CEST
P1116	High complete metabolic response rates with epcoritamab + R-CHOP in previously untreated (1L) patients with high-risk diffuse large b-cell lymphoma, including double/triple-hit: EPCORE NHL-2 update. M. Clausen, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST
P1118	Longer follow-up from the pivotal EPCORE NHL-1 trial reaffirms subcutaneous epcoritamab induces deep, durable complete remissions in patients with relapsed/refractory large B-cell lymphoma. W. Jurczak, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST
P1149	Comparison of the efficacy of epcoritamab versus chimeric antigen receptor therapies, polatuzumab-based regimens, and tafasitamab-based regimens. A. Rosenthal, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST
P1154	Efficacy of subcutaneous epcoritamab vs axi-cel in R/R DLBCL CAR T-naive and CAR T-eligible patients: an indirect comparison. G. Salles, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST
P1169	Comparison of real-world clinical outcomes in patients with relapsed/refractory large B-cell lymphoma treated with epcoritamab vs chemoimmunotherapy. A. Mutebi, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST
P1176	Clinical outcomes of novel therapies in relapsed/refractory diffuse large B-cell lymphoma. T. Wang, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST

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GEN3014 (HexaBody®-CD38):

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
P816	Pharmacodynamic activity of GEN3014 (Hexabody-CD38) in patients with multiple myeloma supports enhanced complement dependent cytotoxicity of GEN3014 compared to daratumumab. I. Hiemstra, et al.	Poster	Friday, June 9, 2023, 6:00 PM - 7:00 PM CEST

About Epcoritamab

Epcoritamab-bysp 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 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.¹ Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration.

Epcoritamab was recently approved in the U.S. under the brand name EPKINLY™ 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 2 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, Genmab announced that AbbVie submitted a Marketing Authorization Application 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, Genmab announced that the company submitted a Japan new drug application 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.

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). Please visit clinicaltrials.gov for more information.

U.S. IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY (epcoritamab-bysp). Initiate treatment with the EPKINLY step-up dosing schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological**

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signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.

Cytokine Release Syndrome (CRS)

- EPKINLY can cause CRS, including serious or life-threatening reactions. CRS occurred in 51% of patients at the recommended dose in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3). Recurrent CRS occurred in 16% of patients. Of all the CRS events, most (92%) occurred during cycle 1. In cycle 1, 9% of CRS events occurred after the 0.16 mg dose (cycle 1, day 1), 16% after the 0.8 mg dose (cycle 1, day 8), 61% after the 48 mg dose (cycle 1, day 15), and 6% after the 48 mg dose (cycle 1, day 22). The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 24 hours (range, 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range, 0-7 days). CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range, 1-27 days).
- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia.
- Initiate EPKINLY according to the step-up dosing schedule. Administer pretreatment medications to reduce the risk of CRS and monitor patients for potential CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS.
- Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS)

- EPKINLY can cause life-threatening and fatal ICANS. ICANS occurred in 6% (10/157) of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal: 1 event). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The median time to onset was 16.5 days (range, 8-141 days) from the start of treatment. Relative to the most recent administration, the median time to onset was 3 days (range, 1-13 days). The median duration of ICANS was 4 days (range, 0-8 days), with ICANS resolving in 90% of patients with supportive care.
- Signs and symptoms of ICANS can include confusional state, lethargy, tremors, dysgraphia, aphasia, and nonconvulsive status epilepticus. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.
- Monitor for potential ICANS. At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines.
- Patients who experience signs or symptoms of ICANS or any other adverse reactions that impair cognition or consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, serious infections, including opportunistic infections, were reported in 15% of patients treated with EPKINLY at the recommended dose (14% grade 3 or 4, 1.3% fatal). The most common grade 3 or greater infections were sepsis, COVID-19, urinary tract infection, pneumonia, and upper respiratory tract infection.

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- Monitor patients for signs and symptoms of infection prior to and during treatment with EPKINLY and treat appropriately. Avoid administration of EPKINLY in patients with active infections.
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.
- Withhold or consider permanent discontinuation of EPKINLY based on severity.

Cytopenias

- EPKINLY can cause serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia. Among patients who received the recommended dose in the clinical trial, grade 3 or 4 events occurred in 32% (decreased neutrophils), 12% (decreased hemoglobin), and 12% (decreased platelets). Febrile neutropenia occurred in 2.5%.
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose.

Adverse Reactions

- The most common ($\geq 20\%$) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

Lactation

- Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.

Please see the full [Prescribing Information](#) and [Medication Guide](#), including Boxed 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](https://twitter.com/Genmab).

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¹ 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