

Genmab Announces Multiple Abstracts to be Presented at the 65th Annual Meeting and Exposition of the American Society of Hematology (ASH)

Media Release

COPENHAGEN, Denmark; November 2, 2023

- Eighteen total abstracts accepted for presentation and publication, including results from four clinical trials evaluating epcoritamab in multiple treatment settings and patient populations
- Oral presentations highlighting new findings from a clinical trial of epcoritamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and a real-world analysis of patients with R/R large B-cell lymphoma (LBCL) will be featured
- Initial data from trial of investigational cancer immunotherapy GEN3014 (HexaBody[®]-CD38) also accepted
- Genmab to host virtual R&D Update and ASH Data Review on December 12

Genmab A/S (Nasdaq: GMA B) announced today that multiple abstracts evaluating epcoritamab (DuoBody[®]-CD3xCD20), a T-cell engaging bispecific antibody administered subcutaneously, across a variety of treatment settings and hematologic malignancies have been accepted for presentation and publication at the 65th Annual Meeting and Exposition of the American Society of Hematology (ASH), being held in San Diego, California, and virtually, December 9-12. The presentations will include two oral and 11 poster presentations highlighting data from several trials evaluating the safety and efficacy of epcoritamab as a monotherapy or in combination for the treatment of patients with various lymphoma subtypes, across lines of therapy including relapsed/refractory (R/R) and newly diagnosed patients.

Additionally, results from a phase 1/2 trial evaluating GEN3014 (HexaBody-CD38), an investigational novel human CD38 monoclonal antibody, in patients with R/R multiple myeloma (MM), will be presented.

All abstracts accepted for presentation have been published on the [ASH website](#).

“The breadth and depth of data accepted for presentation at this year’s American Society of Hematology meeting underline our dedication to comprehensive evaluation of our investigational medicines and reinforce our joint commitment with AbbVie to develop epcoritamab as a potential core therapy for B-cell malignancies,” said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab.

2023 R&D Update and ASH Data Review

On Tuesday, December 12, at 11:00 AM EST (5:00 PM CET/4:00 PM GMT), Genmab will host its 2023 R&D Update and ASH Data Review. The event will be virtual and webcast live. Details, including the webcast link and registration will be available on www.genmab.com. This meeting is not an official program of the ASH Annual Meeting.

Abstracts accepted for presentation at ASH:

Epcoritamab (DuoBody-CD3xCD20)

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
438	Subcutaneous Epcoritamab Plus Lenalidomide in Patients With Relapsed/Refractory Diffuse Large B-cell Lymphoma from EPCORE NHL-5. Avivi, I et al.	Oral	Sunday, December 10, 9:30 - 11:00 AM PT

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1655	Epcoritamab SC Monotherapy Drives Deep and Durable Responses in Patients with Relapsed or Refractory Follicular Lymphoma: Results from the EPCORE NHL-1 Dose Expansion Cohort. Linton KM et al.	Poster	Saturday, December 9, 5:30 - 7:30 PM PT
1729	CRS Mitigation Strategies: Preliminary Results from the DLBCL Optimization Arm A Cohort of EPCORE NHL-1. Vose J et al.	Poster	Saturday, December 9, 5:30 - 7:30 PM PT
3053	EPCORE FL-1: Phase 3 Trial of Subcutaneous Epcoritamab With Rituximab and Lenalidomide (R2) vs R2 Alone in Patients With Relapsed or Refractory Follicular Lymphoma. Falchi L et al.	Poster	Sunday, December 10, 6:00 - 8:00 PM PT
3092	Epcoritamab SC + GemOx Leads to High Complete Metabolic Response Rates in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma Ineligible for Autologous Stem Cell Transplant: Updated Results from EPCORE NHL-2. Brody J, et al.	Poster	Sunday, December 10, 6:00 - 8:00 PM PT
3135	Identification of Optimal Dosing Regimen for Subcutaneous Epcoritamab in Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma. Li, T et al.	Poster	Sunday, December 10, 6:00 - 8:00 PM PT
4481	Population Pharmacokinetics of Subcutaneous Epcoritamab in Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma. Li, T et al.	Poster	Monday, December 11, 6:00 - 8:00 PM PT
4457	Subcutaneous Epcoritamab + R-mini-CHOP in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma Ineligible for Full-Dose Anthracycline: Results from the EPCORE NHL-2 Phase 1/2 Trial. Vermaat JS et al.	Poster	Monday, December 11, 6:00 - 8:00 PM PT

GEN3014 (HexaBody-CD38)

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
4757	GEN3014 (HexaBody [®] -CD38) in Anti-CD38 mAb–Naive Patients with Relapsed/Refractory Multiple Myeloma: Preliminary Results from a Dose-Expansion Cohort of a Phase 1/2 Trial. Grosicki S, et al.	Poster	Monday, December 11, 6:00 - 8:00 PM PT

Outcomes Research

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
309	Effectiveness of Chemo-Immunotherapy (CIT) and Novel Therapies in Second or Later Line of Therapy (2L+) for Patients with Relapsed/Refractory (R/R) Aggressive Large B-cell Lymphoma (LBCL). Nastoupil L et al.	Oral	Saturday, December 9, 4:00 - 5:30 PM PT

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1683	Real-World Response Rates Across Lines of Therapy Among Patients With Relapsed/Refractory Follicular Lymphoma. Philips T et al.	Poster	Saturday, December 9, 5:30 - 7:30 PM PT
1733	Efficacy of Subcutaneous Epcoritamab vs Tisa-cel in R/R LBCL CAR T-naive and CAR T-eligible Patients: An Indirect Comparison. Salles G et al.	Poster	Saturday, December 9, 5:30 - 7:30 PM PT
5089	Cost-Effectiveness of Epcoritamab in Relapsed or Refractory Diffuse Large B-Cell Lymphoma After At Least Two Lines of Therapy in The United States. Qu et al.	Poster	Monday, December 11, 6:00 - 8:00 PM PT
5158	Patterns of Care and Resource Use Among Elderly Relapsed/Refractory Follicular Lymphoma Patients: US Medicare Claims Analysis. Chawla SB, et al.	Poster	Monday, December 11, 6:00 – 8:00 PM PT
NA	Practice Efficiency Associated with Epcoritamab for The Treatment of Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma from an Institutional Perspective. Lei M et al.	Publication	N/A
NA	Estimating the Number of Relapsed/Refractory Follicular Lymphoma Patients on Therapy in the United States. Johnston K et al.	Publication	N/A

Discovery Research

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
NA	Assessment of ultra-deep DIA mass spectrometry-based proteomics compared to flow cytometry and RNA-based methods for the discovery and validation of therapeutic targets in immune cells; Wah Au et al.	Publication	N/A
NA	Unbiased Subtyping of AML: Unraveling Genomic and Transcriptomic Features for Precision Medicine and Targeted Therapies using Beat-AML and TCGA Data; Karagoz et al	Publication	N/A

The safety and efficacy of epcoritamab has not been established for these investigational uses. The safety and efficacy of HexaBody-CD38 has not been established.

About Large B-cell Lymphoma (LBCL)

LBCL is a fast-growing type of non-Hodgkin's lymphoma (NHL), a cancer that develops in the lymphatic system and affects B-cell lymphocytes, a type of white blood cell. There are an estimated 150,000 new LBCL cases each year globally.^{1,2} There are several subtypes of LBCL, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B).

About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of NHL worldwide, accounting for approximately 30 percent of all NHL cases and comprising an estimated 30,400 U.S. cases in 2022. DLBCL can arise in lymph nodes as well as in organs outside of the lymphatic system, occurs more commonly in the elderly and is slightly more prevalent in men.^{1,3} DLBCL is a fast-growing type of NHL, a cancer that develops in the lymphatic system and affects B-cell lymphocytes, a type of white blood cell. For many people living with DLBCL, their cancer either relapses, which means it may return after treatment, or becomes refractory, meaning it does

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not respond to treatment. Although new therapies have become available, treatment management can remain a challenge.^{1,4}

About Follicular Lymphoma (FL)

FL is typically an indolent (or slow growing) form of NHL that arises from B-lymphocytes.⁵ 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.^{6,7} Although FL is an indolent lymphoma, it is considered incurable with conventional therapy.^{8,9}

About Epcoritamab

Epcoritamab (approved as EPKINLY™) 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. EPKINLY 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

EPKINLY (also known as TEPKINLY® in certain countries) has received regulatory approval in various indications and conditions in the U.S., Japan, the European Union, the United Kingdom and Canada. In the U.S., epcoritamab was added to the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a treatment option for diffuse large B-cell lymphoma (DLBCL).

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.

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

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

- **Cytokine release syndrome (CRS)**, which is common during treatment with EPKINLY and can be serious or life-threatening. To help reduce your risk of CRS, you may receive other medicines before receiving EPKINLY and you will also be given smaller doses of EPKINLY for the first 2 doses (called "step-up" dosing). Your first full dose of EPKINLY will be given on day 15 of your first cycle of treatment and you should be hospitalized for 24 hours after due to risk of CRS and neurologic problems. If your dose of EPKINLY is delayed for any reason, you may need to repeat the step-up dosing schedule.
- **Neurologic problems** that can be life-threatening and lead to death. Neurologic problems may happen days or weeks after you receive EPKINLY.

Tell your healthcare provider or get medical help right away if you develop a fever of 100.4°F (38°C) or higher; dizziness or lightheadedness; trouble breathing; chills; fast heartbeat; feeling anxious; headache; confusion; shaking (tremors); problems with balance and movement, such as trouble walking; trouble speaking or writing; confusion and disorientation; drowsiness, tiredness or lack of energy; muscle weakness; seizures; or memory loss. **These may be symptoms of CRS or neurologic problems. Do**

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not drive or use heavy machinery or do other dangerous activities if you have any symptoms that impair consciousness until your symptoms go away.

EPKINLY can cause other serious side effects, including:

- **Infections** that may lead to death. 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** 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 cells (neutropenia), which can increase your risk for infection; low red blood cells (anemia), which can cause tiredness and shortness of breath; and low platelets (thrombocytopenia), which can cause bruising or bleeding problems.

Your healthcare provider will monitor you for symptoms of CRS, neurologic problems, infections, and low blood cell counts during treatment with EPKINLY. 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 your medical conditions, including if you have an infection, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. If you receive EPKINLY while pregnant, it may harm your unborn baby. **If you are a female who can become pregnant,** your healthcare provider should do a pregnancy test before you start treatment with EPKINLY and 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. Do not breastfeed during treatment with EPKINLY and for 4 months after your last dose of EPKINLY.

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 [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](https://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, 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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¹ Sehn LH, Salles G. Diffuse Large B-Cell Lymphoma. *N Engl J Med*. 2021;384:842-858. DOI: 10.1056/NEJMra2027612.

² Martelli M, Ferreri AJM, Agostinelli C, Di Rocco A, Pfreundschuh M, Pileri SA. Diffuse large B-cell lymphoma. *Crit Rev Oncol Hematol*. 2013;87(2):146-171. DOI: 10.1016/j.critrevonc.2012.12.009.

³ Kanas G, Ge W, Quek RGW, Keeven K, Nersesyan K, Arnason JE. Epidemiology of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) in the United States and Western Europe: population-level projections for 2020-2025. *Leuk Lymphoma*. 2022;63(1):54-63. DOI: 10.1080/10428194.2021.1975188.

⁴ Crump M, Neelapu SS, Farooq U, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*. 2017;130(16):1800-1808. DOI: 10.1182/blood-2017-03-769620.

⁵ What is Lymphoma. Lymphoma Research Foundation. <https://lymphoma.org/aboutlymphoma/nhl/fl/>. Accessed October 2023.

⁶ Ma S. Risk factors of follicular lymphoma. *Expert Opin Med Diagn*. 2012;6:323-333. DOI: 10.1517/17530059.2012.686996.

⁷ Luminari S, Bellei M, Biasoli I, Federico M. Follicular lymphoma—treatment and prognostic factors. *Rev Bras Hematol Hemoter*. 2012;34:54-59. DOI: 10.5581/1516-8484.20120015.

⁸ Link BK, Day BM, Zhou X, 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. DOI: 10.1111/bjh.15149.

⁹ Ren J, Asche CV, Shou Y, Galaznik. 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. DOI: 10.2217/cer-2018-0094.

¹⁰ 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.