Test1

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NEWS RELEASE

Genmab to Submit Supplemental Biologics License Application (sBLA) to U.S. Food and Drug Administration for Epcoritamab Plus Rituximab and Lenalidomide (R^2) in Patients with Relapsed/Refractory Follicular Lymphoma (FL)

2025-05-01

- Decision to submit based on a positive overall response rate (ORR) (p-value < 0.0001), one of the dual primary endpoints in the Phase 3 EPCORE® FL-1 trial
- Full results from the trial will be submitted for presentation at an upcoming medical conference in 2025

A/S (Nasdaq: GMAB) announced today its
upplemental Biologics License Application
on (FDA) for subcutaneous epcoritamab, a
h rituximab and lenalidomide (R2) for the treatment of
ymphoma (FL), following at least one prior systemic
therapy.

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The decision to submit the sBLA is supported by positive topline results from the Phase 3 EPCORE FL-1 trial evaluating epcoritamab plus R2 versus R2 alone in adult patients with R/R FL. Based on an interim analysis conducted by an Independent Data Monitoring Committee (IDMC) review, the study met one of its dual primary endpoints of ORR (Complete Response plus Partial Response, p-value < 0.0001). The safety profile of epcoritamab plus R2 in adult patients with R/R FL was consistent with the known safety profiles of the individual regimens (epcoritamab and R2) and as presented in the U.S. prescribing information for epcoritamab. No new safety signals were observed. The full results will be submitted later this year for presentation at an upcoming medical congress and discussed with global regulatory authorities.

“We are pleased with the strength of the data that allows us to submit a supplemental Biologics License Application in accordance with the U.S. FDA’s Project Frontrunner, which supports our commitment to advance novel medicines to patients who need them. The interim topline results demonstrate the potential of this investigational epcoritamab combination regimen to treat relapsed or refractory follicular lymphoma patients,” said Jan van de Winkel, Ph.D., Chief Executive Officer, Genmab. “This milestone represents our commitment to the ongoing development of epcoritamab, with our partner AbbVie, and we look forward to seeing the full results from the study.”

Use of epcoritamab plus R2 in R/R FL is not approved in the U.S., 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. Epcoritamab is currently approved by the FDA under Accelerated Approval as a monotherapy for the treatment of adults with R/R FL after two or more lines of systemic therapy.

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.i About 15,000 people develop FL each year in the U.S.ii and it is considered incurable with current standard of care therapies.iii Patients often relapse and, with each relapse the remission and time to next treatment is shorter.iv 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.v

rventional trial to evaluate the safety and efficacy of
s R2 alone in patients with relapsed/refractory (R/R)
ORR and progression-free survival assessed by
independent review committee (IRC) per Lugano criteria.

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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.vi

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 (R2) in patients with R/R FL (**NCT05409066**), a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R2) 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.

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

What is EPKINLY?

EPKINLY is a prescription medicine used to treat adults with certain types of diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, or follicular lymphoma (FL) that has come back or that did not respond to previous treatment after receiving 2 or more treatments. EPKINLY is approved based on patient response data. Studies are

ot known if EPKINLY is safe and effective in children.

ous 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 will receive EPKINLY on a step-up dosing schedule (when you receive 2 or 3 smaller step-up doses of EPKINLY before your first full dose during your first cycle of treatment), and you may also receive other medicines before and for 3 days after receiving EPKINLY. 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.

People with DLBCL or high-grade B-cell lymphoma should be hospitalized for 24 hours after receiving their first full dose of EPKINLY on day 15 of cycle 1 due to the risk of CRS and neurologic problems.

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

EPKINLY can cause other serious side effects, including:

- Infections that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment and treat you as needed if you develop an infection. You should receive medicines from your healthcare provider before you start treatment to help prevent infection. 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, which 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.

etely stop treatment with EPKINLY if you develop certain

re provider about all your medical conditions,

n 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.

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In DLBCL or high-grade B-cell lymphoma, 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. The most common severe abnormal laboratory test results include decreased white blood cells, decreased red blood cells, and decreased platelets.

In follicular lymphoma the most common side effects of EPKINLY include injection site reactions, CRS, COVID-19, tiredness, upper respiratory tract infections, muscle and bone pain, rash, diarrhea, fever, cough, and headache. The most common severe abnormal laboratory test results include decreased white blood cells and decreased red blood cells.

These are not all of 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.

Globally, prescribing information varies; refer to the individual country product label for complete 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 more than 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

is to transform the lives of people with cancer and other
dy medicines®.

hagen, Denmark, with international presence across North
please visit **Genmab.com** and follow us on **LinkedIn** and **X**.
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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 preclinical 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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i Lymphoma Research Foundation official website. **https://lymphoma.org/aboutlymphoma/nhl/fl/**. Accessed November 2024.
ii Leukemia & Lymphoma Society. **https://www.lls.org/research/follicular-lymphoma-fl**. Accessed November 2024.
iii Ghione P, Palomba ML, Ghesquieres H, et al. Treatment patterns and outcomes in relapsed/refractory follicular lymphoma: results from the international SCHOLAR-5 study. Haematologica. 2023;108(3):822-832. doi: 10.3324/haematol.2022.281421.
iv Rivas-Delgado A, Magnano L, Moreno-Velázquez M, et al. Response duration and survival shorten after each relapse in patients with follicular lymphoma treated in the rituximab era. Br J Haematol. 2018;184(5):753-759. doi:10.1111/bjh.15708.
v Al-Tourah AJ, Gill KK, Chhanabhai M, et al. Population-based analysis of incidence and outcome of transformed non-Hodgkin's lymphoma. J Clin Oncol. 2008 Nov 10;26(32):5165-9. doi: 10.1200/JCO.2008.16.0283. Epub 2008 Oct 6. PMID: 18838711.
vi Engelberts PJ, 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.

businesswire.com/news/home/20250501833016/en/

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