# Genmab Announces U.S. Food and Drug Administration Granted Orphan-Drug Designation to Epcoritamab (DuoBody®-CD3xCD20) in Follicular Lymphoma

**Media Release**

**COPENHAGEN, Denmark; March 8, 2022**

**Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to the investigational medicine, epcoritamab (DuoBody®-CD3xCD20), for the treatment of follicular lymphoma (FL).** Epcoritamab is being co-developed by Genmab and AbbVie (NYSE: ABBV).

Orphan drug status is designated by the FDA to medicines and biologics that are defined as those intended for the prevention, diagnosis, or treatment of a rare disease or condition affecting less than 200,000 people in the U.S.[i]

Approximately 2.7 per 100,000 people in the U.S. are newly diagnosed with follicular lymphoma (FL)[ii] every year and the median age of patients at diagnoses with FL is 63.[iii,iv,v] FL is typically a slow-growing or indolent form of non-Hodgkin's lymphoma (NHL) that arises from B-lymphocytes.[vi] Although FL is an indolent lymphoma, patients who relapse or become refractory are incurable with conventional therapy and there is a need for additional treatment options.[vii,viii] Globally, FL is the second most common form of NHL, accounting for approximately 25 percent of adult NHL.[ix]

"This orphan drug designation is an important milestone for epcoritamab," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "With AbbVie, we remain committed to further developing epcoritamab in this patient population, as well as in patients diagnosed with other B-cell hematologic malignancies."

Epcoritamab is currently being evaluated as a treatment option for patients with FL in several clinical trials, including the phase 1/2 EPCORE™ NHL-1 evaluating the efficacy and safety of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin's lymphoma (B-NHL), including diffuse large B-cell Lymphoma (DLCBL), follicular lymphoma (FL), and mantle cell lymphoma (MCL) (NCT: 03625037). Additional trials evaluating epcoritamab in patients with FL include a phase 1b/2, open-label, multinational, interventional trial to evaluate the safety and preliminary efficacy of epcoritamab in combination with other standard of care (SOC) agents across different lines of therapy in patients with DLBCL or FL (NCT: 04663347) and a phase 1/2 trial evaluating the safety and efficacy of epcoritamab in Japanese patients with relapsed/refractory B-NHL (NCT: 04542824).

**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 tumors to elicit an immune response towards malignant cells. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T cell mediated killing of lymphoma B cells.[x] CD20 is a clinically validated therapeutic target, and is expressed on many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.[xi,xii] Epcoritamab is an investigational medicine not currently approved by the FDA. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' broad oncology collaboration.

**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

# Genmab Announces U.S. Food and Drug Administration Granted Orphan-Drug Designation to Epcoritamab (DuoBody®-CD3xCD20) in Follicular Lymphoma

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.

**Contact:**
Marisol Peron, Senior Vice President, Global Investor Relations & Communications
T: +1 609 524 0065; E: mmp@genmab.com

**For Investor Relations:**
Andrew Carlsen, Vice President, Head of Investor Relations
T: +45 3377 9558; E: acn@genmab.com

*This Media Release 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 Media Release 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.*



---

[i] Food and Drug Administration official website. Accessed at https://www.fda.gov/industry/developing-products-rare-diseases-conditions. Accessed March 2022.
[ii] National Institutes of Health official website: SEER Cancer Statistics. https://seer.cancer.gov/statfacts/html/follicular.html. Accessed March 2022.
[iii] National Institutes of Health official website: SEER Cancer Statistics. https://seer.cancer.gov/csr/1975_2017/. Table 19.29. Accessed July 2020.
[iv] Cancer Stat Facts: Follicular Lymphoma. https://seer.cancer.gov/statfacts/html/follicular.html x
[v] SEER Cancer Statistics. https://seer.cancer.gov/csr/1975_2017/. Table 19.26. Accessed January 2021.
[vi] Lymphoma Research Foundation official website. Accessed at https://lymphoma.org/aboutlymphoma/nhl/fl/ on March 2022.
[vii] Link BK, 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.
[viii] Ren J, et al. 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.
[ix] Swerdlow SH, Berger F, Pileri S, et al. Lymphoplasmacytic lymphoma. In: Swerdlow SH, Campo E, Harris NL, editors. WHO Classification of Tumors of Haematopoietic and
Lymphoid Tissues. Lyon, France: IARC; 2008.

# Genmab Announces U.S. Food and Drug Administration Granted Orphan-Drug Designation to Epcoritamab (DuoBody®-CD3xCD20) in Follicular Lymphoma

---

[x]Engelbert 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 Feb;52: 102625. doi: 10.1016/j.ebiom.2019.102625. Epub 2020 Jan 23. PMID: 31981978; PMCID: PMC6992935.
[xi]Rafiq, Sarwish, et al. "Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties." Journal of Immunology (Baltimore, Md. 1950), U.S. National Library of Medicine, 15 Mar. 2013, www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/.
[xii]Singh, Vijay, et al. "Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response." Journal of Cancer Science & Therapy, U.S. National Library of Medicine, Nov. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/.