

Genmab Announces Johnson & Johnson Decision Regarding HexaBody®-CD38

Company Announcement

- **Johnson & Johnson has decided that it will not exercise its option to receive a worldwide license to develop, manufacture and commercialize HexaBody-CD38**
- **Genmab will not pursue further clinical development of HexaBody-CD38**
- **Data validates clinical potential of the HexaBody platform**
- **Genmab to host a conference call today at 5:00 PM CET / 4:00 PM GMT / 12:00 PM EDT**

COPENHAGEN, Denmark; March 10, 2025 – [Genmab A/S](#) (Nasdaq: **GMAB) announced today that Johnson & Johnson (J&J) has decided that it will not exercise its option to receive a worldwide license to develop, manufacture and commercialize HexaBody-CD38 (GEN3014).** While the initial HexaBody-CD38 clinical data is promising and showed robust clinical efficacy, following a thorough evaluation of the data, the market landscape, and Genmab's rigorous portfolio prioritization, Genmab will not pursue further clinical development of HexaBody-CD38.

“While we are disappointed that J&J has decided not to advance HexaBody-CD38, the data confirms the clinical potential of the HexaBody platform, reinforcing its value for future applications,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “With EPKINLY® (epcoritamab) moving from strength to strength and two wholly owned assets, rinatabart sesutecan (Rina-S™) and acasunlimab in Phase 3 development, we are confident in the potential of our existing pipeline of innovative antibody therapeutics. Genmab intends to maintain its laser sharp focus on and disciplined investments in our promising late-stage proprietary clinical pipeline and continues to execute against our capital allocation framework ensuring future growth.”

As stipulated by the development and option agreement between Genmab and J&J for HexaBody-CD38, Genmab provided J&J with data from a clinical proof-of-concept study in multiple myeloma, including a head-to-head comparison with DARZALEX FASPRO® (daratumumab and hyaluronidase fhj).

The Phase 2 expansion Part B of the study assessed the objective response rate (primary endpoint) of intravenous HexaBody-CD38 versus subcutaneous daratumumab in patients with anti-CD38 antibody-naïve relapsed or refractory multiple myeloma.

Preliminary data submitted by Genmab to J&J, inclusive of 88 patients who received a study treatment and 84 patients who were response evaluable (42 in each arm), demonstrated an overall response rate (ORR) of 55% (95% CI: 39%, 70%) in the HexaBody-CD38 IV arm vs. 52% in the daratumumab SC arm (95% CI: 36%, 68%); very good partial response (VGPR) or better rate was 29% vs. 17%; and complete response (CR) or better rate was 7% vs. 2%.

Due to the relatively short follow-up time, secondary efficacy endpoints including duration of response, progression-free survival, and overall survival were not mature yet. Treatment emergent Adverse events (TEAEs) above 20% in the HexaBody-CD38 arm were neutropenia, infusion related reactions, anemia, and thrombocytopenia. No new safety findings were observed in the daratumumab arm of the study. TEAEs leading to death included one patient in the HexaBody-CD38 IV arm and two patients in the daratumumab SC arm; none of these deaths was related to the study treatment. Follow-up is ongoing and more mature data will be presented at a future medical conference.

This news does not impact Genmab's 2025 Financial Guidance.

Conference Call Details

Genmab will host a conference call to discuss this event today at 5:00 PM CET / 4:00 PM GMT / 12:00

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PM EDT. To join the call or listen to the webcast, please register using the following link: <https://genmab-investor-update-mar2025.open-exchange.net/>.

An archived webcast of the call will be available at <https://www.genmab.com/investor-relations>.

About the 3014-01 Trial

3014-01 is a Phase 1/2, open-label, multi-center trial to evaluate the safety and preliminary efficacy of HexaBody-CD38 as a monotherapy in patients with relapsed or refractory multiple myeloma and other blood cancers. The trial consists of three parts: a dose-escalation phase (Phase 1) and an expansion phase (Part A and Part B). The primary objective of Phase 1 is to determine the recommended Phase 2 dose and the maximum tolerated dose as well as establish the safety profile of HexaBody-CD38 monotherapy. The purpose of Phase 2 Expansion Part A is to assess the objective response rate of HexaBody-CD38 for patients with relapsed or refractory multiple myeloma and other blood cancers. The purpose of Phase 2 Expansion Part B is to assess the objective response rate of HexaBody-CD38 versus subcutaneous daratumumab in patients with CD38 antibody naïve relapsed or refractory multiple myeloma. More information on this trial can be found at <https://www.clinicaltrials.gov> (NCT04824794).

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 function-enhanced antibodies. 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 international presence across North America, Europe and Asia Pacific. For more information, 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.

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®, Genmab in combination with the Y-shaped Genmab logo®, HuMax®, DuoBody®, HexaBody®, DuoHexaBody®, HexElect® and KYSO®. DARZALEX FASPRO®

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