Genmab Announces New Data Demonstrating Investigational Rinatabart Sesutecan (Rina-S®) Achieved Anti-Tumor Activity in Heavily Pretreated Patients with Advanced Endometrial Cancer

Media Release

COPENHAGEN, Denmark; October 18, 2025

- **Updated data from the Phase 1/2 RAINFOL™-01 trial showed rinatabart sesutecan (Rina-S®) 100 mg/m² demonstrated 50% confirmed objective response rate (ORR), including two complete responses (CR), regardless of FRα expression**
- **A Phase 3 trial in endometrial cancer is underway**
- **U.S. FDA recently granted Breakthrough Therapy Designation to Rina-S for advanced endometrial cancer**

Genmab A/S (Nasdaq: GMAB) announced today updated data from cohort B2 of the Phase 1/2 RAINFOL™-01 trial evaluating rinatabart sesutecan (Rina-S®), an investigational folate receptor alpha (FRα)-targeted, TOPO1-inhibitor antibody-drug conjugate (ADC). The study showed that at a median study follow-up of one year, treatment with Rina-S 100 mg/m² every 3 weeks (Q3W) resulted in a 50.0% confirmed objective response rate (ORR), including two complete responses (CR), in heavily pretreated patients with advanced endometrial cancer (EC) who had progressed following platinum-based chemotherapy and an immune checkpoint inhibitor. Additionally, at a median study follow-up of one year, 63.6% of responders (including CRs) in the 100 mg/m² cohort maintained their responses and remain on treatment. The responses were observed regardless of FRα expression levels. The updated results were presented at the European Society for Medical Oncology (ESMO) Congress in Berlin, Germany.

Continued evaluation of single-agent Rina-S 100 mg/m² in patients with advanced EC is ongoing in the Phase 2 RAINFOL-01 trial (NCT05579366) and the Phase 3 RAINFOL-03 trial (NCT07166094).

“Women with advanced endometrial cancer are often facing a difficult path, while doctors are confronted with not having enough treatment options,” said Noelle Cloven, M.D., Texas Oncology Fort Worth, Sarah Cannon Research Institute, and study investigator. “That’s why these data signals with Rina-S in the updated Phase 1/2 RAINFOL-01 data are encouraging – they point to the possibility of providing more choices for patients in the future.”

The B2 cohort of the Phase 1/2 RAINFOL-01 study (NCT05579366) is a dose expansion cohort evaluating the efficacy and safety of Rina-S in patients with advanced or recurrent endometrial cancer. In the study, 64 patients with heavily pretreated advanced or recurrent endometrial cancer whose disease had progressed on or after an

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anti-PD-(L)1 and platinum-based chemotherapy were enrolled and treated with Rina-S. Patients were administered either 100 mg/m^2 (n=22) (selected dose for Phase 3 clinical trial) or 120 mg/m^2 (n=42) of Rina-S. In the 100 mg/m^2 cohort, the confirmed ORR was 50.0%, including two CRs. Anti-tumor activity was also observed in patients treated with Rina-S 120 mg/m^2 Q3W, which resulted in 44.1% confirmed ORR and one CR. Study participants were previously treated with a median of three lines of therapy (range 1-8). Earlier results from this cohort were previously presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

Common treatment emergent adverse events (TEAEs; all grades) consisted primarily of cytopenias and low-grade gastrointestinal (GI) events. To date, there have been no signals of ocular toxicities, neuropathy, or interstitial lung disease (ILD) observed in Rina-S clinical trials consistent with prior reports. Serious TEAEs (Grade 3 or higher), occurred in 36.4% and 52.4% of patients treated with Rina-S 100 mg/m^2 and 120 mg/m^2, respectively. Hematologic adverse events did not require significant dose reduction and were associated with low rates of treatment discontinuation.

“With this updated data, we are seeing additional momentum behind the possibilities of Rina-S,” said Tahi Ahmadi, M.D., Executive Vice President and Chief Medical Officer, Head of Experimental Medicines at Genmab. “As a wholly owned, novel antibody-drug conjugate, Rina-S reflects Genmab’s vision to accelerate our innovative, late-stage pipeline that has the potential to redefine possibilities for patients with certain gynecologic cancers.”

Rina-S is advancing through late-stage development supported by a growing portfolio of clinical trials, including the ongoing Phase 1/2 RAINFOL-01 trial (NCT05579366), the Phase 3 RAINFOL-03 trial (NCT07166094) in patients with endometrial cancer now underway and the Phase 3 RAINFOL-02 trial (NCT06619236) in patients with platinum resistant ovarian cancer (PROC). The U.S. Food and Drug Administration (FDA) recently granted Breakthrough Therapy Designation (BTD) to Rina-S for the treatment of adult patients with recurrent or progressive EC who have disease progression on or following prior treatment with a platinum-containing regimen and a PD-(L)1 therapy.

About the RAINFOL™ -01 Trial

RAINFOL™-01 (NCT05579366) is an open-label, multicenter Phase 1/2 study, designed to evaluate the safety and efficacy of rinatabart sesutecan (Rina-S) Q3W at various doses in solid tumors that are known to express FRα. The study consists of multiple parts including Part A dose escalation; Part B tumor-specific monotherapy dose-expansion cohorts; Part C platinum-resistant ovarian cancer (PROC) cohort; Part D combination therapy cohorts; Part F a monotherapy endometrial cancer (EC) cohort.

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About Endometrial Cancer

Endometrial cancer (EC) starts in the lining of the uterus, known as the endometrium[i] and ranks as the second most prevalent gynecologic cancer globally, with increasing incidence and mortality rates[ii,iii]. Patients with advanced or recurrent EC have a relatively poor prognosis and treatment options are limited for those patients who have progressed following treatment with chemotherapy and immune checkpoint inhibitor. FRα is overexpressed on multiple tumors, including EC, making it a promising therapeutic target. Anti-tumor activity with Rina-S was observed across a broad range of FRα expression, and there are currently no approved FRα-directed therapies approved for the treatment of endometrial cancer.

About Rinatabart Sesutecan (Rina-S; GEN1184)

Rinatabart sesutecan (Rina-S; GEN1184) is an investigational ADC. It is composed of a novel human monoclonal antibody directed at folate receptor α (FRα), a novel hydrophilic protease-cleavable linker, and exatecan, a topoisomerase I inhibitor payload. The clinical trial program for Rina-S continues to expand including ovarian, endometrial and other cancers of unmet need.

The safety and efficacy of rinatabart sesutecan has not been established. Please visit www.clinicaltrials.gov for more 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 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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[i] Mayo Clinic. Endometrial Cancer. https://www.mayoclinic.org/diseases-conditions/endometrial-cancer/symptoms-causes/syc-20352461.

ii Ferlay J, Ervik M, Lam F, et al. Global cancer observatory: Cancer today (version 1.1). International Agency for Research on Cancer. 05/28/2024 (https://gco.iarc.who.int/today).

iii Concin N, Matias-Guiu X, Vergote I, et al. ESGO/ESTRO/ESP guidelines for the management of patients with endometrial carcinoma. International journal of gynecological cancer : official journal of the International Gynecological Cancer Society 2021;31(1):12-39. (In eng). DOI: 10.1136/ijgc-2020-002230.