# Investigational Rinatabart Sesutecan (Rina-S®) Continues to Show Encouraging Antitumor Activity in Patients with Advanced Ovarian Cancer

## Media Release

**COPENHAGEN, Denmark; March 17, 2025**

- **Results from Phase 2 RAINFOL™-01 trial (B1 cohort) showed that with a median on-study follow-up of 48 weeks, Rina-S 120 mg/m² led to a confirmed objective response rate (ORR) of 55.6% and median duration of response (mDOR) was not reached**
- **Phase 2 RAINFOL™-01 and Phase 3 RAINFOL™-02 trials evaluating the safety and efficacy of Rina-S at 120 mg/m² in patients with platinum resistant ovarian cancer (PROC) are actively recruiting**

**Genmab A/S (Nasdaq: GMAB)** announced today updated data from cohort B1 of the Phase 1/2 RAINFOL-01 study of rinatabart sesutecan (Rina-S®), an investigational folate receptor-alpha (FRα)-targeted, TOPO1 antibody-drug conjugate (ADC) that showed Rina-S 120 mg/m² every 3 weeks (Q3W) resulted in a confirmed objective response rate (ORR) of 55.6% (95% CI: 30.8-78.5) in heavily pre-treated ovarian cancer (OC) patients regardless of FRα expression levels. With a median on-study follow-up of 48 weeks, 1 out of 10 patients experienced disease progression and the median duration of response (mDOR) was not reached (95% CI: 40.14-NR). The data are from the dose expansion cohort of the multi-part study evaluating the safety and efficacy of Rina-S as a single agent in solid tumors that are known to express FRα and were presented at the 2025 Society of Gynecologic Oncology Annual Meeting on Women's Cancer® (SGO) in Seattle, Washington.

"The antitumor activity observed in the dose expansion cohort continues to demonstrate the potential for a much-needed treatment option for patients with PROC, who have historically had poor prognosis. I am hopeful that further exploration of Rina-S will lead to advancements in the treatment landscape." said Elizabeth Lee, M.D., a medical oncologist in the gynecologic oncology program at Dana-Farber.

The B1 cohort is a dose expansion study in patients with histologically or cytologically confirmed advanced OC (epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer). Rina-S 120 mg/m² Q3W at a median on-study follow-up of 48 weeks showed encouraging antitumor activity; the confirmed ORR was 55.6% (95% CI: 30.8-78.5), the disease control rate (DCR) was 88.9% (95% CI: 65.3-98.6), and the median duration of response (mDOR) was not reached (95% CI: 40.14-NR). In the 18 patients evaluable for response treated with 120 mg/m² Q3W, complete responses were observed in 4 patients (2 confirmed; 2 unconfirmed) and 8 patients experienced confirmed partial responses (44.4%). Most responses with Rina-S 120 mg/m² were observed early (at week 6). Only one patient in the 120 mg/m² treatment arm was not evaluable. In the Rina-S 100 mg/m² Q3W treatment arm (N=22), at a median on study follow-up of 46 weeks, the confirmed ORR was 22.7% (95% CI: 7.8-45.4), the DCR was 86.4% (95% CI: 65.1-97.1), and the mDOR was not reached (95% CI, 16.3-NR). Partial responses were observed in 4 patients (18.2%) and 1 patient (4.5%) experienced a complete response. Rina-S 120 mg/m² has been selected for further evaluation in the RAINFOL-01 and Phase 3 RAINFOL-02 trials for patients with platinum resistant ovarian cancer (PROC).

In this Phase 1/2 study, common treatment-emergent adverse events (TEAEs) included anemia, nausea, neutropenia, leukopenia, fatigue, thrombocytopenia, vomiting, diarrhea, alopecia, and hypokalemia. Dose reductions and treatment discontinuations were infrequent and no new safety signals were observed.

"The updated results reinforce the potential of Rina-S and further validate our development approach in advanced ovarian cancer," said Judith Klimovsky, M.D., Executive Vice President and Chief Development Officer of Genmab. "We are excited to keep moving forward with the ongoing Phase 3 trial, to evaluate the potential of Rina-S as a treatment option for patients facing this challenging disease."

# Investigational Rinatabart Sesutecan (Rina-S®) Continues to Show Encouraging Antitumor Activity in Patients with Advanced Ovarian Cancer

The safety and efficacy of rinatabart sesutecan has not been established for these investigational uses.

**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) as a single agent Q3W at various doses in solid tumors that are known to express FRα. The study consists of multiple parts including Part A dose-escalation cohorts; Part B tumor-specific monotherapy dose-expansion cohorts; Part C platinum-resistant ovarian cancer (PROC) cohort; and Part D combination therapy cohorts.

Part B of the trial includes the B1 cohort, a dose expansion study in patients with histologically or cytologically confirmed advanced OC (epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer). Patients were randomized 1:1 to 100 mg/m$^2$ and 120 mg/m$^2$ dose cohorts. Median age was 62.5 and 64.5 years in the 100 mg/m$^2$ and 120 mg/m$^2$ cohorts, respectively. Study participants were previously treated with a median of 3 prior lines of therapy (range 1-4). Patients received prior treatment with bevacizumab (90.9% in the 100 mg/m$^2$ group and 90.0% in the 120 mg/m$^2$ group respectively), PARP inhibitors (68.2%; 65%), and mirvetuximab soravtansin (18.2%; 19%). Initial results from Part B of this trial were presented during a mini-oral session at the European Society of Medical Oncology Congress 2024 (ESMO).

**About Ovarian Cancer**
Ovarian cancer is a major global health issue, with over 320,000 new cases diagnosed annually worldwide.[i] It ranks as the eighth most common cancer and the eighth leading cause of cancer-related deaths among women globally.[ii] The disease is often diagnosed at an advanced stage due to its subtle and non-specific symptoms, such as abdominal bloating, pelvic pain and difficulty eating.[iii] Standard of care for platinum resistant ovarian cancer typically involves single agent chemotherapy (pegylated liposomal doxorubicin (PLD), topotecan, gemcitabine or paclitaxel).[iv] Approximately 70-90% of women with advanced-stage ovarian cancer worldwide experience a recurrence after initial treatment.[v] Ovarian cancer has a low five-year survival rate, which varies significantly by region, but generally hovers around 30-50%.[vi,vii]

**About Rinatabart Sesutecan (Rina-S®; GEN1184)**
Rinatabart sesutecan (Rina-S; GEN1184) is a FRα-targeted, TOPO1 ADC, currently being evaluated for the potential treatment of ovarian cancer and other FRα-expressing cancers. A Phase 3 trial (RAINFOL-02, NCT06619236) evaluating Rina-S in patients with platinum resistant ovarian cancer compared to treatment of investigator's choice is ongoing. In January 2024, the U.S. Food and Drug Administration granted Fast Track designation to Rina-S for the treatment of patients with FRα-expressing high-grade serous or endometrioid platinum-resistant ovarian cancer.

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®.

# Investigational Rinatabart Sesutecan (Rina-S®) Continues to Show Encouraging Antitumor Activity in Patients with Advanced Ovarian Cancer

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.

**Contact:**
David Freundel, Senior Director, Global Communications & Corporate Affairs
T: +1 609 430 2481; E: dafr@genmab.com

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 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 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] World Cancer Research Fund International. https://www.wcrf.org/cancer-trends/ovarian-cancer-statistics/. Accessed August 2024.
[ii] World Ovarian Cancer Coalition. https://worldovariancancercoalition.org/about-ovarian-cancer/key-stats/. Accessed August 2024.
[iii] Dilley, James et al. Ovarian cancer symptoms, routes to diagnosis and survival - Population cohort study in the 'no screen' arm of the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). *Gynecologic oncology* vol. 158,2 (2020): 316-322. doi:10.1016/j.ygyno.2020.05.002.
[iv] Eskander RN, Moore KN, Monk BJ, Herzog TJ, Annunziata CM, O'Malley DM and Coleman RL (2023) Overcoming the challenges of drug development in platinum-resistant ovarian cancer. Front. Oncol. 13:1258228
Ovarian Cancer Research Alliance. https://ocrahope.org/patients/diagnosis-and-treatment/recurrence/.
[v] Ovarian Cancer Research Alliance. https://ocrahope.org/patients/diagnosis-and-treatment/recurrence/.
[vi] European Institute of Women's Health. https://eurohealth.ie/policy-brief-women-and-ovarian-cancer-in-the-eu-2018/. Accessed August 2024.
[vii] American Cancer Society. Stages of Ovarian Cancer. https://www.cancer.org/cancer/types/ovarian-cancer/detection-diagnosis-staging/survival-rates.html. Accessed August 2024.