

Genmab Announces Rinatabart Sesutecan (Rina-S®) Phase 2 RAINFOL™-01 Results Demonstrated Durable and Clinically Meaningful Responses in Patients with Platinum-Resistant Ovarian Cancer

Media Release

COPENHAGEN, Denmark; October 3, 2026

- **Treatment with Rina-S® 120 mg/m² every three weeks demonstrated a clinically meaningful objective response rate (ORR) and durable median duration of response (mDOR) in patients with platinum-resistant ovarian cancer (PROC)**
- **Antitumor activity was observed regardless of folate receptor alpha (FRα) expression levels, including low FRα expression and non-expressors**

Genmab A/S (Nasdaq: **GMAB**) today announced results from Part C of the Phase 1/2 RAINFOL™-01 trial evaluating rinatabart sesutecan (Rina-S), an investigational folate receptor alpha (FRα)-targeted, topoisomerase I (TOPO1)-inhibitor antibody-drug conjugate (ADC), demonstrated that among 109 treated patients with platinum-resistant ovarian cancer (PROC), Rina-S achieved a confirmed objective response rate (ORR) of 45.9% (95% CI: 36.3–55.7), including five complete responses (CRs) and a median duration of response (mDOR) of 12.1 months (95% CI: 6.5–15.4), with 51% of responders remaining in response at one year. The findings were presented today in a Late-Breaking Oral Session at the International Gynecologic Cancer Society (IGCS) Congress 2026, held in Montreal, Canada.

The study also demonstrated a median progression-free survival (mPFS) of 9.5 months (95% CI: 7.6–11.3). Antitumor activity was observed regardless of FRα expression levels, including in patients with low FRα expression and non-expressors, and regardless of prior treatment with mirvetuximab.

“Platinum-resistant ovarian cancer is a difficult-to-treat disease. As patients relapse and progress through successive lines of therapy, achieving durable clinical benefit becomes increasingly challenging, yet remains critically important,” said Elizabeth K. Lee, M.D., study investigator and a medical oncologist in the gynecologic oncology program at Dana-Farber Cancer Institute. “The antitumor activity and durability observed with Rina-S in this heavily pretreated population are encouraging and suggest the potential to meaningfully impact outcomes for patients facing a particularly challenging stage of disease.”

The Part C cohort of the Phase 1/2 RAINFOL-01 study evaluated Rina-S 120 mg/m² Q3W as monotherapy in patients with platinum-resistant high-grade serous ovarian, primary peritoneal, or fallopian tube cancer. Eligible patients received one to three prior lines of therapy; patients who received mirvetuximab as their last prior therapy could have received up to four prior lines. More than half of patients (53%) had received three or four prior lines of therapy. All patients had received prior bevacizumab and taxane therapy; 49.5% had received a prior PARP inhibitor, and 33% had received prior mirvetuximab soravtansine. Median follow-up exceeded one year.

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The most common treatment-emergent adverse events (TEAEs) included fatigue (57.8%) and low-grade (Grade 1-2) gastrointestinal events, such as nausea (67.9%), vomiting (36.7%), constipation (26.6%), decreased appetite (23.9%), and abdominal pain (18.3%). The most frequently reported hematologic TEAEs included anemia (57.8%), neutropenia (57.8%), decreased platelet count (34.9%), and thrombocytopenia (34.9%). Serious adverse events (SAEs) were reported in approximately one-third of participants. Treatment discontinuation due to TEAEs occurred in 5.5% of participants. No safety signals for ocular toxicity, peripheral neuropathy, interstitial lung disease (ILD), or stomatitis were observed.

“The late-breaking results presented today add an important layer of evidence to the growing clinical experience with Rina-S in patients with platinum-resistant ovarian cancer,” said Tahamtan Ahmadi, M.D., Ph.D., Executive Vice President and Chief Medical Officer, Head of Experimental Medicines, Genmab. “These findings, including the observed antitumor activity, duration of response, and the first progression-free survival data reported for the program, as well as the manageable tolerability, reinforce the potential of Rina-S. As our Phase 3 program continues to advance, the results further inform our evaluation of Rina-S as a potential treatment option for patients with gynecologic cancers.”

Rina-S is being evaluated in a broad clinical development program spanning multiple gynecologic cancers and other solid tumors. The program includes four Phase 3 trials evaluating Rina-S in PROC (RAINFOL-02; [NCT06619236](#)), recurrent or progressive endometrial cancer (RAINFOL-03; [NCT07166094](#)), platinum-sensitive ovarian cancer (PSOC) maintenance therapy (RAINFOL-04; [NCT07225270](#)), and second-line PSOC (RAINFOL-07; [NCT07564141](#)). Additional studies include the Phase 1/2 RAINFOL-01 trial ([NCT05579366](#)) and Phase 2 trials in non-small cell lung cancer (RAINFOL-05; [NCT07288177](#)) and advanced gastrointestinal cancers (RAINFOL-09; [NCT07539311](#)).

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 Rina-S Q3W at various doses in selected solid tumors, including tumors across a range of FR α expression levels. The study consists of multiple parts, including the PROC monotherapy cohort.

About Ovarian Cancer

Ovarian cancer (OC) is a major global health issue, with more than 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 because its symptoms, including abdominal bloating, pelvic pain, and difficulty eating, can be subtle and nonspecific.ⁱⁱⁱ Approximately 70-90% of women with advanced-stage OC worldwide experience a recurrence after initial treatment.^{iv} OC has a low five-year survival rate, which varies significantly by region, but generally hovers around 30-50%.^{v,vi}

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About Rinatabart Sesutecan (Rina-S; GEN1184)

Rina-S (GEN1184) is an investigational ADC. It is composed of a novel human monoclonal antibody directed at FR α , a hydrophilic protease-cleavable linker, and exatecan, a TOPO1 inhibitor payload. The clinical trial program for Rina-S continues to expand, including ovarian, endometrial, and other cancers with unmet need.

The safety and efficacy of Rina-S have not been established. Please visit <https://clinicaltrials.gov/> for more information.

About Genmab

Genmab is an international biotechnology company dedicated to improving the lives of people with cancer and other serious diseases through innovative antibody medicines. For over 25 years, its passionate, innovative and collaborative team has advanced a broad range of antibody-based therapeutic formats, including bispecific antibodies, antibody-drug conjugates (ADCs), immune-modulating antibodies and other next-generation modalities. Genmab's science powers eight approved antibody medicines, and the company is advancing a strong late-stage clinical pipeline, including wholly owned programs, with the goal of delivering transformative medicines to patients.

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 or follow us on [LinkedIn](#), [X](#), [Facebook](#) and [Instagram](#).

Contact:

David Freundel, Senior Director, Global Communications & Corporate Affairs
T: +1 609 613 0504; E: dafr@genmab.com

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

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ⁱ World Cancer Research Fund International. <https://www.wcrf.org/cancer-trends/ovarian-cancer-statistics/>. Accessed Oct 2025.

ⁱⁱ World Ovarian Cancer Coalition. <https://worldovariancancercoalition.org/about-ovarian-cancer/key-stats/>. Accessed Oct 2025.

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} Ovarian Cancer Research Alliance. <https://ocrahope.org/patients/diagnosis-and-treatment/recurrence/>

^v European Institute of Women's Health. <https://eurohealth.ie/policy-brief-women-and-ovarian-cancer-in-the-eu-2018/>. Accessed Oct 2025.

^{vi} American Cancer Society. Stages of Ovarian Cancer. <https://www.cancer.org/cancer/types/ovarian-cancer/detection-diagnosis-staging/survival-rates.html>. Accessed Oct 2025.