

Genmab Presents the Safety and Tolerability of Rinatabart Sesutecan (Rina-S®) in Combination with Bevacizumab in Advanced Ovarian Cancer

Media Release

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- Phase 1/2 RAINFOL™-01 data showed the combination of rinatabart sesutecan (Rina-S®) and bevacizumab was tolerable, with no new safety signals in patients with advanced ovarian cancer
- The ongoing Phase 3 RAINFOL-04 trial will further evaluate the combination in patients with recurrent platinum-sensitive ovarian cancer (PSOC)

Genmab A/S (Nasdaq: GMAB) announced today new data demonstrating that rinatabart sesutecan (Rina-S®), an investigational folate receptor alpha (FR α)-targeted, topoisomerase I (TOPO1)-inhibitor antibody-drug conjugate (ADC), evaluated in combination with bevacizumab in patients with advanced ovarian cancer, showed a safety profile consistent with the known safety profiles of Rina-S and bevacizumab. These data are from the combination therapy cohort D2 of the multi-part Phase 1/2 RAINFOL™-01 study and were presented during an oral session at the 2026 Society of Gynecologic Oncology Annual Meeting on Women's Cancer (SGO) in San Juan, Puerto Rico.

“Advanced ovarian cancer is a complex and difficult-to-treat disease, and the ability for investigational therapies such as Rina-S to be safely combined with bevacizumab can provide clinicians with more options to help improve disease control and manage resistance,” said Cara Mathews, M.D., study investigator and Associate Professor, Obstetrics and Gynecology at the Women and Infants Hospital, Brown University. “Rina-S has shown a manageable safety profile as a monotherapy, and these safety data suggest that it may be combined with a standard-of-care therapy such as bevacizumab without significantly increasing the risk of additional side effects.”

As of data cutoff, 40 patients with recurrent ovarian cancer had received Rina-S (120 mg/m²) plus bevacizumab every three weeks until disease progression or unacceptable toxicity. The primary endpoint was safety and tolerability. The combination of Rina-S and bevacizumab was tolerable, with manageable adverse events (AEs). The safety profile of the combination was consistent with the known safety profiles of the individual agents, with no new or unexpected safety signals. The most common ($\geq 25\%$) treatment-emergent AEs (TEAEs) included nausea (80%), fatigue (67.5%), anemia (55%), and neutropenia (45%). No safety signals of ocular toxicities, peripheral neuropathy or interstitial lung disease were reported, and no clinically significant bleeding was observed. Serious TEAEs occurred in six patients (15.0%), and TEAEs leading to Rina-S dose reductions occurred in 11 patients (27.5%). Rina-S and bevacizumab discontinuation occurred in two patients (5%). No fatal TEAEs were reported.

“Today's safety results from RAINFOL-01 add to the growing body of clinical evidence supporting further development of Rina-S in advanced ovarian cancer, including its potential to be used in a combination regimen,” said Tahamtan Ahmadi, M.D., Ph.D., Executive Vice President and Chief Medical Officer, Head of Experimental Medicines, Genmab. “Rina-S has the potential to meaningfully expand treatment possibilities for patients with certain gynecologic cancers, and we look forward to further investigating additional opportunities, alone and with other therapies, as Rina-S advances through late-stage clinical development.”

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-02 trial ([NCT06619236](#)) in patients with platinum-resistant ovarian cancer (PROC), the Phase 3 RAINFOL-03 trial ([NCT07166094](#)) in patients with recurrent or progressive endometrial cancer (EC) who have disease progression on or following prior treatment with a platinum-containing regimen and a PD-(L)1 therapy,

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and the Phase 3 RAINFOL-04 trial ([NCT07225270](https://clinicaltrials.gov/ct2/show/study/NCT07225270)) in patients with recurrent platinum-sensitive ovarian cancer (PSOC) as maintenance therapy. Rina-S is also being evaluated in the Phase 2 RAINFOL-05 study ([NCT07288177](https://clinicaltrials.gov/ct2/show/study/NCT07288177)) in patients with non-small cell lung cancer (NSCLC).

About the RAINFOL-01 Trial

RAINFOL-01 ([NCT05579366](https://clinicaltrials.gov/ct2/show/study/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 solid tumors that are known to express FR α . The study consists of multiple parts including Part D combination therapy cohorts.

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 PROC typically involves single-agent chemotherapy (pegylated liposomal doxorubicin (PLD), topotecan, gemcitabine or paclitaxel) and mirvetuximab for FR α -positive ($\geq 75\%$ positive tumor cells) patients.^{iv,v} Approximately 70-90% of women with advanced-stage ovarian cancer worldwide experience a recurrence after initial treatment.^{vi} Ovarian cancer has a low five-year survival rate, which varies significantly by region, but generally hovers around 30-50%.^{vii,viii}

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 has 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](https://www.genmab.com) and follow us on [LinkedIn](#) and [X](#).

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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} 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.

^v National Comprehensive Cancer Network (NCCN). NCCN Guidelines for Patients®: Ovarian Cancer. Version 3.2024. July 15, 2024. <https://www.nccn.org/patients/guidelines/content/PDF/ovarian-patient.pdf>

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

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

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