Genmab Announces Rinatabart Sesutecan (Rina-S®) Demonstrates Statistically Significant Improvement in Progression-Free Survival and Overall Survival in Patients with Platinum-Resistant Ovarian Cancer

Company Announcement

COPENHAGEN, Denmark; October 23, 2026

- **Phase 3 RAINFOL™-02 trial met its primary endpoint of progression-free survival (PFS) and its key secondary endpoint of overall survival (OS) with rinatabart sesutecan (Rina-S®) compared to investigator's choice chemotherapy**
- **Results demonstrated statistically significant and clinically meaningful improvement in PFS and OS in patients with platinum-resistant ovarian cancer (PROC)**
- **Data will be submitted for presentation at a future medical meeting and discussed with regulatory authorities worldwide**

Genmab A/S (Nasdaq: GMAB) announced today positive topline results from the global Phase 3 RAINFOL™-02 trial of rinatabart sesutecan (Rina-S®), an investigational folate receptor alpha (FRα)-targeted, topoisomerase I (TOPO1)-inhibitor antibody-drug conjugate (ADC), in patients with platinum-resistant ovarian cancer (PROC) regardless of FRα expression level or prior treatment with mirvetuximab. The trial met its primary endpoint of progression-free survival (PFS), with Rina-S demonstrating a statistically significant and clinically meaningful improvement compared with investigator's choice chemotherapy in the intent-to-treat (ITT) and in the primary analysis set (PAS) populations.

The ITT population (N=584) comprised of all randomized patients with PROC, regardless of FRα expression. The PAS population (N=492) mandated patients with FRα expression ≥75% PS2+ to have been treated with mirvetuximab.

In the ITT population, Rina-S demonstrated a 71% reduction in the risk of disease progression or death (HR 0.29; 95% CI, 0.23-0.37; p<0.0001). In the PAS population, Rina-S demonstrated a 67% reduction in the risk of disease progression or death (HR 0.33; 95% CI, 0.26–0.42; p<0.0001).

The study also met its key secondary endpoint of overall survival (OS), demonstrating a statically significant and clinically meaningful improvement in the ITT population (HR 0.43; 95% CI, 0.31–0.59; p<0.0001) and in the PAS population (HR 0.44; 95% CI, 0.31–0.63; p<0.0001).

The observed safety profile was consistent with the known profile of Rina-S, with no new safety signals or unexpected safety concerns identified.

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"As the first Phase 3 readout from our Rina-S program, the positive topline results from RAINFOL-02 mark a significant milestone for Genmab and strengthen our confidence in Rina-S's potential for patients with platinum-resistant ovarian cancer. These results advance our ambition to become a leader in gynecologic oncology and reflect our commitment to improving the lives of patients with high unmet medical needs," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We look forward to discussing these results and potential next steps with regulatory authorities worldwide. We are deeply grateful to the patients, caregivers, and investigators whose participation made this study possible."

Based on these results, Genmab plans to engage with regulatory authorities worldwide regarding potential next steps. The data will also be submitted for presentation at a future medical meeting.

"Platinum-resistant ovarian cancer remains one of the greatest challenges in gynecologic oncology, with patients often facing a poor prognosis and limited effective treatment options. The Phase 3 RAINFOL-02 results set a new benchmark in addressing this urgent unmet need regardless of FRα expression," said Angeles Alvarez Secord, MD, MHSc, the study's lead investigator for the Gynecologic Oncology Group (GOG) and Professor of Obstetrics and Gynecology at the Duke Cancer Institute. "The 71% reduction in the risk of disease progression and 57% reduction in the risk of death underscore the potential of Rina-S to change clinical practice if approved by offering a therapeutic option for a broad patient population."

Rina-S is being evaluated in a broad clinical development program spanning multiple gynecologic cancers and other solid tumors. The program includes five 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), second-line PSOC (RAINFOL-07; NCT07564141), and in first-line ovarian cancer as maintenance therapy (RAINFOL-10; NCT07859215). 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).

On Wednesday, October 28 at 5:00 p.m. CET/12:00 p.m. EDT, Genmab will host an investor update. To register, visit genmab.com/events-presentations.

About the RAINFOL-02 Trial
The RAINFOL-02/GOG 3107/ENGOT OV86 study was conducted in close collaboration with the Gynecologic Oncology Group (GOG) Foundation, European Network of Gynaecological Oncological Trial Groups (ENGOT), and centers from Asia-Pacific.

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RAINFOL-02 (NCT06619236) is a global, randomized, open-label, multicenter Phase 3 study evaluating the efficacy and safety of Rina-S versus investigator's choice chemotherapy in 584 patients with PROC regardless of FRα expression level. Patients are randomized 1:1 to receive either Rina-S 120 mg/m² on Day 1 of each three-week treatment cycle or one of four standard-of-care chemotherapy agents: paclitaxel, topotecan, PLD, or gemcitabine. The primary endpoint is investigator-assessed PFS. Key secondary endpoints are OS and objective response rate (ORR). Other secondary endpoints include PFS by blinded independent central review, duration of response, incidence of adverse events and laboratory abnormalities, time from randomization to second disease progression or death, and change from baseline in global health status/quality of life. Efficacy is evaluated in two populations. The ITT population (N=584) includes all randomized patients, regardless of FRα expression level. The PAS (N=492), a subset of the ITT population, includes only patients with FRα expression <75% PS2+ and patients previously treated with mirvetuximab if eligible based on FRα expression ≥75% PS2+ and available in the region.

About Ovarian Cancer

Ovarian cancer (OC) is a major global health issue, 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]

About Rinatabart Sesutecan (Rina-S; GEN1184)

Rina-S (GEN1184) is an investigational ADC. It is composed of a novel human monoclonal antibody directed at FRα, 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, 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 and follow us on LinkedIn, *X*, Facebook and Instagram.

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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.

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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.