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GSK presents positive data for Mo-Rez in platinum-resistant ovarian cancer

- 62% confirmed objective response rate and 12.2-month median duration of response in phase Ib trial
- 11.1-month median progression-free survival in a difficult-to-treat setting
- Five pivotal phase III studies now underway across gynaecological cancers

GSK plc (LSE/NYSE: GSK) today announced updated data from the global phase I BEHOLD-1 trial for mocertatug rezetecan (Mo-Rez), an investigational B7-H4-targeted antibody-drug conjugate (ADC). Results showed clinically meaningful and durable responses at >13 months follow-up, building on initial data in platinum-resistant ovarian cancer (PROC) announced earlier this year. These data will be presented in a late-breaking oral session at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain.¹

Mo-Rez achieved a confirmed objective response rate (cORR) of 62% (n=28/45; 95% confidence interval [CI]: 46.5-76.2%), with a median duration of response (DoR) of 12.2 months (95% CI: 7.0-12.7) at the selected phase III dose of 5.8 mg/kg. Median progression-free survival (PFS) was 11.1 months (95% CI: 8.3-13.9).¹

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: “Current treatment options for patients with platinum-resistant ovarian cancer are limited and achieving durable responses remains a challenge. These promising results for Mo-Rez show that treatment responses and durability are maintained over time in many patients, alongside encouraging progression-free survival and a manageable safety profile. We have accelerated the phase III development programme across gynaecological cancers, with five pivotal studies now underway.”

Safety results remain consistent with previously published data.² Grade ≥3 treatment-related adverse events (TRAEs) were observed in 71% (n=32/45) of patients and were predominantly haematologic. At the selected phase III dose, TRAEs led to treatment discontinuation in 2% (n=1/45) of patients treated and interstitial lung disease (ILD)/pneumonitis occurred in 2% (n=1/45) of patients.¹

Vanda Salutari, Study Investigator for BEHOLD-1, Innovative Therapies Unit for Female Cancers, Department of Women and Child Health, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy said: “Despite advances in ovarian cancer, platinum-resistant disease is one of the hardest to treat, and many patients still experience limited benefit from available treatment options. The duration of response and progression-free survival observed in BEHOLD-1 are particularly encouraging relative to what is typically seen in this setting where prolonged disease control remains difficult to achieve.”

B7-H4 is an immune checkpoint that is widely expressed in gynaecological cancers and is low in normal tissues. The responses to Mo-Rez observed across a range of B7-H4 expression levels support its broad potential in gynaecological cancers and an accelerated large-scale phase III programme is now underway in ovarian and endometrial cancers.

Additional data from the BEHOLD programme being presented at ESMO include an exploratory biomarker analysis from BEHOLD-1 showing responses across a range of B7-H4 expression levels and study designs for the phase III BEHOLD-Ovarian01 and BEHOLD-Endometrial01 studies.^{3,4,5} The BEHOLD-1 results support the selected 5.8 mg/kg dose being evaluated in the phase III development programme.



About the BEHOLD clinical trial programme

The BEHOLD clinical programme is GSK's global development plan that includes the BEHOLD-1 (NCT06431594) monotherapy study and the ongoing BEHOLD-2 (NCT06796907) combination study.

Five pivotal phase III trials are currently underway:

- Platinum-resistant ovarian cancer (BEHOLD-Ovarian01 / NCT07286266)
- Platinum-sensitive ovarian cancer (BEHOLD-Ovarian02 / NCT07684612)
- First-line maintenance setting for ovarian cancer without homologous recombination deficiency (BEHOLD-Ovarian03 / NCT07694427)
- Second-line advanced and recurrent endometrial cancer (BEHOLD-Endometrial01 / NCT07286331)
- First-line maintenance setting mismatch repair proficient endometrial cancer (BEHOLD-Endometrial02 / NCT07684599).

About BEHOLD-1

The BEHOLD-1 clinical trial is a two-part, open-label, phase I study evaluating the safety, tolerability and efficacy of Mo-Rez injection in patients with platinum-resistant ovarian cancer (PROC) or advanced/recurrent endometrial cancer (EC). Phase Ia assessed up to four Mo-Rez dose levels in patients with advanced solid tumours, with intravenous administration every three weeks until progression or toxicity. In the phase Ib dose expansion, patients with PROC or EC (1-3 prior lines of therapy) were randomised to three or two Mo-Rez dose levels, respectively.

At data cut-off, a total of 136 PROC patients were enrolled in BEHOLD-1. At the selected phase III dose evaluated in phase Ib, the most common adverse events in PROC were gastrointestinal and haematological, consistent with treatments in this class. Treatment-related adverse events led to dose interruptions in 51% of patients with PROC and dose reductions in 47%. Primary endpoints included: incidence of dose-limiting toxicity in phase Ia and confirmed objective response rate (cORR) by investigator per RECIST 1.1 in phase Ib. Patients with EC treated at the selected phase III dose continue to be followed, with data expected to be presented in the future.

About mocertatug rezetecan

Mo-Rez is a novel investigational B7-H4-targeted antibody-drug conjugate designed to optimise efficacy and tolerability. It is composed of a fully human anti-B7-H4 monoclonal antibody covalently linked to a topoisomerase inhibitor payload and has a drug-to-antibody ratio (DAR) of 6. GSK acquired exclusive worldwide rights (excluding mainland China, Hong Kong, Macau and Taiwan) from Hansoh Pharma to progress clinical development and commercialisation of Mo-Rez globally.

About ovarian cancer

Ovarian cancer affects 843,000 people with 240,000 new cases annually.⁶ 70% of people living with ovarian cancer will present with advanced disease and survival usually declines after recurrence.^{7,8} Patients with platinum-resistant ovarian cancer (PROC), one of the hardest to treat, face limited treatment options and poor outcomes.⁹ Many will develop resistance to platinum-based chemotherapy, the backbone of first-line treatment, underscoring the need for innovations that can deliver meaningful benefit.⁹

GSK in oncology

GSK is focused on developing differentiated medicines for cancers where patients continue to face poor outcomes, treatment resistance, limited options or significant treatment burden. We focus where advances in science and technology offer the greatest opportunity to improve outcomes across haematological, lung, gastrointestinal, genitourinary and gynaecological cancers. Across multiple modalities, including targeted small molecules, antibody-drug conjugates (ADCs) and immunotherapies, GSK applies deep expertise in cancer biology and immune system science to develop differentiated medicines designed to deliver durable responses, overcome resistance and reduce treatment burden.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at www.gsk.com.

Press release

For media and investors only



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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q2 Results for 2026.

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