Press release

For media and investors only

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GSK presents positive data for B7-H4-targeted ADC in gynaecological cancers

- Mocertatug rezetecan achieved confirmed objective response rates of 62% in platinum-resistant ovarian cancer (PROC) and 67% in recurrent or advanced endometrial cancer (EC) in BEHOLD-1 study
- Current treatment options are limited for patients with PROC and EC
- Promising efficacy and safety profile supports start of five pivotal phase III trials in 2026

GSK plc (LSE/NYSE: GSK) today announced positive findings from its global phase I BEHOLD-1 clinical trial for mocertatug rezetecan (or Mo-Rez for short), a novel antibody-drug conjugate (ADC) targeting the B7-H4 antigen. At the highest doses evaluated, Mo-Rez monotherapy achieved confirmed objective response rates (cORR) of 62% (5.8 mg/kg n=21/34; 95% CI: 44, 78) in platinum-resistant ovarian cancer (PROC) and 67% (4.8 mg/kg n=8/12; 95% CI: 35, 90) in recurrent or advanced endometrial cancer (EC).[1] These data will be presented for the first time in a late-breaking oral session at the Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer in San Juan, Puerto Rico.

Currently, there are limited treatment options with modest response rates for patients with PROC and advanced EC. B7-H4 is an immune checkpoint that is widely expressed in ovarian and endometrial cancers and is low in normal tissues, providing potential for a differentiated precision-therapy. The response to Mo-Rez observed across a range of B7-H4 expression levels reinforces its broad potential in gynaecologic cancers and further validates the relevance of targeting B7-H4.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Treatment of gynaecological cancers remains a major challenge, with a pressing need for new therapies that offer improved response rates. With Mo-Rez, we now have compelling evidence of a promising clinical profile, with response rates that support accelerating development into five pivotal global phase III trials later this year across ovarian and endometrial cancers, including earlier-line settings."

Ana Oaknin, Study Investigator for BEHOLD-1, Medical Oncology Department, Hospital Universitario Puerta de Hierro-Majadahonda, Madrid, Spain said: "In the early phase BEHOLD-1 study, we saw meaningful antitumour activity for this patient dataset, with response rates higher than typically seen in ADCs in development, and a manageable safety profile. For patients with platinum-resistant ovarian cancer and recurrent endometrial cancer, these findings are particularly encouraging."

At the highest doses evaluated in BEHOLD-1, few patients needed to stop treatment because of a treatment-related adverse events (TRAE) (0% in PROC and 4% in EC). The most common TRAE was nausea (82% in PROC; 75% in EC). Grade ≥3 TRAEs occurred in 64% and 54% patients in PROC and EC, respectively, and were predominantly haematologic, as expected for treatments in this class. Overall rates of interstitial lung disease or pneumonitis were low (3%; 5 out of 178 patients) and all cases were mild to moderate (grade 1-2). The interim analysis showed the median duration of response had not yet been reached. Based on the findings from this study, the recommended dose for the first of the phase III trials, BEHOLD-Ovarian01 and BEHOLD-Endometrial01, is 5.8 mg/kg.

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. Mo-Rez will advance to five pivotal global phase III trials in 2026, starting with PROC (BEHOLD-Ovarian01 / NCT07286266) and 2L EC (BEHOLD-Endometrial01 / NCT07286331). Additional phase III studies will evaluate Mo-Rez in platinum-sensitive ovarian cancer (BEHOLD-Ovarian02) and in first-line maintenance settings for ovarian cancer without homologous recombination deficiency (BEHOLD-Ovarian03) and mismatch-repair–proficient endometrial cancer (BEHOLD-Endometrial02).

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 PROC or advanced/recurrent 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 224 patients were enrolled in BEHOLD-1; n=44 in phase Ia (n=21 PROC, n=23 mix of other solid tumours) and n=180 in phase Ib (n=131 PROC, n=49 EC). Primary endpoints included: incidence of dose-limiting toxicity in phase Ia and confirmed ORR (cORR) by investigator per RECIST 1.1 in phase Ib. At the highest dose evaluated in phase Ib, the most common adverse events in PROC were nausea (86%), neutropenia/neutrophil count decreased (73%), anaemia (52%), fatigue (52%) and alopecia (52%). In EC, the most common adverse events were nausea (79%), neutropenia/neutrophil count decreased (58%), anaemia (54%), vomiting (46%) and fatigue (42%). Treatment-related adverse events led to dose interruptions in 39% of patients with PROC and 21% of those with EC, and to dose reductions in 39% in PROC and 17% in EC, at the highest dose. The trial is ongoing and currently in the dose expansion phase.

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 China's mainland, Hong Kong, Macau, and Taiwan) from Hansoh Pharma to progress clinical development and commercialisation of Mo-Rez globally.

About ovarian cancer and endometrial cancer

Endometrial cancer affects 1.6 million people globally, with 417,000 new cases each year and 15% to 20% of patients presenting in later stages of the disease.[2,3] Ovarian cancer affects 843,000 people with 240,000 new cases annually.[4] 70% of these patients present with advanced disease.[5] Recurrence is common in advanced cases of disease, up to 67% in endometrial cancer and 70% in ovarian cancer, and survival usually declines after recurrence.[6,7]

GSK in oncology

Our ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates targeting B7-H3 and B7-H4, and IDRX-42, a highly selective KIT tyrosine kinase inhibitor.

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.

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