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US FDA accepts for priority review GSK's application for an expanded indication of *Jemperli* (dostarlimab) plus chemotherapy to include all adult patients with primary advanced or recurrent endometrial cancer

- Application supported by statistically significant and clinically meaningful progression-free and overall survival data from phase III RUBY Part 1 trial
- Dostarlimab plus chemotherapy is the only immuno-oncology-based therapy to show a statistically significant and clinically meaningful survival benefit in the overall patient population
- 23 August 2024 assigned as Prescription Drug User Fee Act action date for FDA decision

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) accepted the supplemental Biologics License Application (sBLA) for *Jemperli* (dostarlimab) in combination with standard-of-care chemotherapy (carboplatin and paclitaxel) to expand treatment to all adult patients with primary advanced or recurrent endometrial cancer. This would include patients with mismatch repair proficient (MMRp)/microsatellite stable (MSS) tumours.

Currently, *Jemperli* is FDA-approved in combination with carboplatin and paclitaxel, followed by *Jemperli* as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is either mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).

The FDA granted Priority Review for this application and assigned a Prescription Drug User Fee Act action date of 23 August 2024.

The sBLA is based on results from Part 1 of the RUBY phase III trial. The trial met its primary endpoints of investigator-assessed progression-free survival (PFS) and overall survival (OS), demonstrating a statistically significant and clinically meaningful benefit in the overall population of patients treated with dostarlimab plus carboplatin-paclitaxel versus chemotherapy alone. RUBY Part 1 is the only clinical trial to show a statistically significant survival benefit in the overall patient population. The safety and tolerability analysis from RUBY showed a safety profile for dostarlimab and carboplatin-paclitaxel that was generally consistent with the known safety profiles of the individual agents.

OS data were presented at the Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer on 16 March 2024.

About endometrial cancer

Endometrial cancer is found in the inner lining of the uterus, known as the endometrium. Endometrial cancer is the most common gynaecologic cancer in developed countries, with approximately 417,000 new cases reported each year worldwide¹, and incidence rates are expected to rise by almost 40% between 2020 and 2040.^{2,3} Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of

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diagnosis.⁴ Among patients with primary advanced or recurrent endometrial cancer, approximately 70-75% have MMRp/MSS tumours.⁵

About RUBY

RUBY is a two-part global, randomised, double-blind, multicentre phase III trial of patients with primary advanced or recurrent endometrial cancer. Part 1 is evaluating dostarlimab plus carboplatin-paclitaxel followed by dostarlimab versus carboplatin-paclitaxel plus placebo followed by placebo. Part 2 is evaluating dostarlimab plus carboplatin-paclitaxel followed by dostarlimab plus niraparib versus placebo plus carboplatin-paclitaxel followed by placebo.

In Part 1, the dual-primary endpoints are investigator-assessed PFS based on the Response Evaluation Criteria in Solid Tumours v1.1 and OS. The statistical analysis plan included pre-specified analyses of PFS in the dMMR/MSI-H and overall populations and OS in the overall population. Pre-specified exploratory analyses of PFS and OS in the MMRp/MSS population and OS in the dMMR/MSI-H populations were also performed. RUBY Part 1 included a broad population, including histologies often excluded from clinical trials and had approximately 10% of patients with carcinosarcoma and 20% with serous carcinoma.

In Part 2, the primary endpoint is investigator-assessed PFS in the overall population, followed by PFS in the MMRp/MSS population, and OS in the overall population is a key secondary endpoint. Additional secondary endpoints in Part 1 and Part 2 include PFS per blinded independent central review, PFS2, overall response rate, duration of response, disease control rate, patient-reported outcomes, and safety and tolerability.

RUBY is part of an international collaboration between the European Network of Gynaecological Oncological Trial groups (ENGOT), a research network of the European Society of Gynaecological Oncology (ESGO) that consists of 22 trial groups from 31 European countries that perform cooperative clinical trials, and the GOG Foundation, a non-profit organisation dedicated to transforming the standard of care in gynaecologic oncology.

About *Jemperli* (dostarlimab)

Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2.⁶

In the US, *Jemperli* is indicated in combination with carboplatin and paclitaxel, followed by *Jemperli* as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is dMMR, as determined by a US FDA-approved test, or MSI-H, and as a single agent for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by a US FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation. The sBLA supporting this indication in combination with carboplatin and paclitaxel for dMMR/MSI-H primary advanced or recurrent endometrial cancer received Breakthrough Therapy designation and Priority Review from the US FDA. *Jemperli* is also indicated in the US for patients with dMMR recurrent or advanced solid tumours, as determined by a US FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The latter indication is approved in the US under accelerated approval based on tumour response rate and durability of response. Continued approval for this indication in solid tumours may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Jemperli was discovered by AnaptysBio, Inc. and licensed to TESARO, Inc., under a collaboration and exclusive license agreement signed in March 2014. Under this agreement, GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of *Jemperli*, and cobolimab (GSK4069889), a TIM-3 antagonist.

Please see accompanying US Prescribing Information.

GSK in oncology

Oncology is an emerging therapeutic area for GSK where we are committed to maximising patient survival with a current focus on haematologic malignancies, gynaecologic cancers and other solid tumours through breakthroughs in immuno-oncology and tumour-cell targeting therapies.

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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 [gsk.com](https://www.gsk.com).

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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 under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2023.

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