# GSK receives US FDA file acceptance for Jemperli (dostarlimab) plus chemotherapy for the treatment of dMMR/MSI-H primary advanced or recurrent endometrial cancer

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BY GSK

For media and investors only

- Submission accepted for Priority Review

- Breakthrough Therapy designation granted for this potential indication

- Application being reviewed under the FDA Project Orbis framework, which enables concurrent reviews among US, Australia, Canada, Switzerland, Singapore and United Kingdom health authorities

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 chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer. If approved in this patient population, dostarlimab plus chemotherapy could represent the first meaningful frontline treatment advancement in decades for patients with primary advanced or recurrent endometrial cancer.

The FDA granted Priority Review for this application and assigned a Prescription Drug User Fee Act action date of 23 September 2023. Dostarlimab also was recently granted Breakthrough Therapy designation for this potential new indication.

Under Project Orbis, an initiative from the FDA Oncology Center of

Excellence that provides a framework for concurrent submission and review of oncology products among international partners, the dostarlimab sBLA will be reviewed by health authorities in the US, Australia, Canada, Switzerland, Singapore and the United Kingdom.

Hesham Abdullah, Senior Vice President, Global Head of Oncology Development, GSK said:

> We are excited about this initial filing for this potential new indication for dostarlimab in the patient population that demonstrated the strongest treatment effect in the phase III RUBY trial. Long-term outcomes for patients with primary advanced or recurrent endometrial cancer remain poor, and there is an urgent need to evolve the current standard of care, which is platinum-based chemotherapy. We look forward to working with the FDA and other health authorities as they review this application.

Endometrial cancer is the most common gynaecologic cancer in developed countries, and there are about 60,000 new cases of endometrial cancer diagnosed every year in the US. Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis. An estimated 20-29% of all endometrial cancers are dMMR/MSI-H. Chemotherapy used alone is the current standard of care for primary advanced or recurrent endometrial cancer, and many patients eventually experience disease progression.

Currently, in endometrial cancer, dostarlimab is approved in the US as monotherapy in dMMR recurrent or advanced endometrial cancer that has progressed on or following a prior platinum-containing regimen. If the sBLA is approved, dostarlimab could potentially be indicated earlier in treatment in combination with platinum-containing chemotherapy for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer.

The sBLA is based on the prespecified interim analysis results from Part 1 of the RUBY/ENGOT-EN6/GOG3031/NSGO phase III trial. The trial met its primary endpoint of investigator-assessed progression-free survival (PFS), which demonstrated a statistically significant and clinically meaningful benefit in patients treated with dostarlimab plus carboplatin-paclitaxel in the dMMR/MSI-H population and in the overall population. The data reflect a robust median duration of follow-

up of ≥24.8 months. 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. These data were presented at the European Society for Medical Oncology (ESMO) Virtual Plenary and the Society of Gynecologic Oncology (SGO) Annual Meeting on 27 March 2023, and were simultaneously published in The New England Journal of Medicine.

Part 1 of the RUBY trial continues to assess the dual-primary endpoint of overall survival (OS) in the intent-to-treat (ITT) population. At the first interim analysis in the ITT population, a clinically meaningful OS trend was observed among patients receiving dostarlimab plus chemotherapy followed by dostarlimab. The OS analysis was done at 33% maturity and statistical significance was not reached.

In April, the European Medicines Agency (EMA) validated GSK's marketing authorisation application for dostarlimab plus chemotherapy for the treatment of dMMR/MSI-H primary advanced or recurrent endometrial cancer.

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. The dual-primary endpoints in Part 1 are investigator-assessed PFS based on the Response Evaluation Criteria in Solid Tumours v1.1 and overall survival (OS). The statistical analysis plan included pre-specified analyses of PFS in the dMMR/MSI-H and intent-to-treat (ITT) populations and OS in the overall population. Pre-specified exploratory analyses of PFS in the mismatch repair proficient (MMRp)/microsatellite stable (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. Secondary endpoints in Part 1 and Part 2 include PFS per blinded independent central review, overall response rate, duration of response, disease control rate, patient-reported

outcomes, and safety and tolerability.

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.

In the US, Jemperli is indicated for adult patients with mismatch repair-deficient (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. 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. The collaboration has resulted in three monospecific antibody therapies that have progressed into the clinic. These are: Jemperli (GSK4057190), a PD-1 antagonist; cobolimab, (GSK4069889), a TIM-3 antagonist; and GSK4074386, a LAG-3 antagonist. GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of each of these medicines under the agreement.

Please see accompanying US Prescribing Information.

GSK is committed to maximising patient survival through transformational medicines. GSK’s pipeline is focused on immuno-oncology, tumour cell targeting therapies and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, and antibody-drug conjugates, either alone or in combination.

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.

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 2022, GSK's Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

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