Press release

For media and investors only

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Jemperli (dostarlimab) plus chemotherapy receives positive CHMP opinion to expand approval to all adult patients with primary advanced or recurrent endometrial cancer

- Positive opinion based on statistically significant and clinically meaningful progression-free and overall survival data from phase III RUBY trial
- An expanded approval would include MMRp/MSS tumours, which represent majority of endometrial cancer cases
- Approval decision expected in Q1 2025

GSK plc (LSE/NYSE: GSK) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended expanding the approval of *Jemperli* (dostarlimab) in combination with chemotherapy (carboplatin and paclitaxel) for first-line treatment of all adult patients with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy. This would include patients with mismatch repair proficient (MMRp)/microsatellite stable (MSS) tumours, who represent 70-75% of patients diagnosed with endometrial cancer and who have limited treatment options.

The CHMP opinion is one of the final steps prior to a marketing authorisation decision by the European Commission, with an approval decision expected in the first quarter of 2025.

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

OS data were presented at the Society of Gynecologic Oncology Annual Meeting on Women's Cancer on 16 March 2024, and were published in *Annals of Oncology* on 9 June 2024. The label for *Jemperli* in the US was expanded to all adult patients with primary advanced or recurrent endometrial cancer in August 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,[1] with an estimated 1.6 million people living with active disease at any stage and 417,000 new cases reported each year worldwide.[2] Incidence rates are expected to rise by approximately 40% between 2020 and 2040.[3] In Europe, approximately 121,000 people are estimated to be diagnosed with primary advanced or recurrent endometrial cancer each year.[4] Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.[5] Among patients with primary advanced or recurrent endometrial cancer, approximately 70-75% have MMRp/MSS tumours.[6]

About RUBY

RUBY is a two-part global, randomised, double-blind, multicentre phase III trial of 785 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, a programmed death receptor-1 (PD-1)-blocking antibody, is the backbone of GSK's ongoing immuno-oncology-based research and development programme. A robust clinical trial programme includes studies of *Jemperli* alone and in combination with other therapies in gynaecologic, colorectal and lung cancers, as well as where there are opportunities for transformational outcomes.

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. This includes patients with MMRp/MSS and dMMR/MSI-H tumours. *Jemperli* is also approved 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. Additionally, *Jemperli* is 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.

Important Information for *Jemperli* in the EU

Indication

Jemperli is indicated:

- in combination with carboplatin and paclitaxel, for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy;
- as monotherapy for treating adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

Refer to the *Jemperli* EMA Reference Information for a full list of adverse events and the complete important safety information in the EU.

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.

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.

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