Press release

For media and investors only

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European Commission expands *Jemperli* (dostarlimab) plus chemotherapy approval to all adult patients with primary advanced or recurrent endometrial cancer

- Expanded approval includes MMRp/MSS tumours, which represent approximately 75% of endometrial cancer cases
- Approval based on RUBY Part 1 trial, which showed a median overall survival (OS) of 44.6 months for *Jemperli* plus chemotherapy vs. 28.2 months for chemotherapy alone
- *Jemperli* plus chemotherapy is the only immuno-oncology-based treatment to show statistically significant and clinically meaningful OS benefit in the overall population

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GSK plc (LSE/NYSE: GSK) today announced the European Commission has approved *Jemperli* (dostarlimab) in combination with chemotherapy (carboplatin and paclitaxel) for first-line treatment of adult patients with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy. This approval broadens the previous indication for *Jemperli* plus chemotherapy in the European Union (EU) to include patients with mismatch repair proficient (MMRp)/microsatellite stable (MSS) tumours, which represent approximately 75% of patients diagnosed with endometrial cancer and who have limited treatment options.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "For the first time, all patients with primary advanced or recurrent endometrial cancer in the EU have an approved immuno-oncology-based treatment that has shown a statistically significant and clinically meaningful overall survival benefit. We're proud *Jemperli* continues to redefine the treatment landscape for patients."

Dr Mansoor Raza Mirza, Chief Oncologist, Copenhagen University Hospital, Denmark, and RUBY principal investigator said: "Clinicians have been waiting for years for an immuno-oncology-based option that can meaningfully improve overall survival outcomes for patients with MMRp/MSS primary advanced or recurrent endometrial cancer. The expanded approval represents a significant advance that delivers on this hope, now for patients with both dMMR/MSI-H and MMRp/MSS tumours."

The European Commission's approval to expand the use of *Jemperli* plus chemotherapy is based on results from Part 1 of the RUBY phase III trial. RUBY Part 1 is the only clinical trial in this setting to show a clinically meaningful and statistically significant overall survival (OS) benefit in the full population of patients with primary advanced or recurrent endometrial cancer, demonstrating a 31% reduction in risk of death (HR: 0.69; 95% CI: 0.54–0.89) compared to chemotherapy alone.

At the 2.5-year landmark, the chance of being alive was 61% (95% CI: 54-67) for patients in the *Jemperli* plus chemotherapy group (245 patients) compared to 49% (95% CI: 43-55) in the chemotherapy group (249 patients). In addition, a 16.4-month improvement in median OS was observed with *Jemperli* plus chemotherapy versus chemotherapy alone (44.6 months [95% CI: 32.6–NR] vs. 28.2 months [95% CI: 22.1–35.6], respectively). The median duration of follow-up was more than three years.[1] The safety and tolerability analysis from RUBY Part 1

showed a safety profile for *Jemperli* plus carboplatin-paclitaxel that was generally consistent with the known safety profiles of the individual agents. The most common treatment-emergent adverse reactions (≥ 10%) in patients receiving *Jemperli* plus chemotherapy were rash, rash maculopapular, hypothyroidism, pyrexia, alanine aminotransferase increased, aspartate aminotransferase increased and dry skin.

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* plus chemotherapy 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,[2] with an estimated 1.6 million people living with active disease at any stage and 417,000 new cases reported each year worldwide.[3] Incidence rates are expected to rise by approximately 40% between 2020 and 2040.[4] In Europe, approximately 121,000 people are estimated to be diagnosed with primary advanced or recurrent endometrial cancer each year.[5] Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.[6] Among patients with primary advanced or recurrent endometrial cancer, approximately 75% have MMRp/MSS tumours.[7]

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 progression-free survival (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 mismatch repair deficient (dMMR)/microsatellite instability-high (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 first-line treatment of adult patients with 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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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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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