# GSK to demonstrate its commitment to improving outcomes for patients with gynaecologic cancer at the 2022 SGO Annual Meeting

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- Data presentations will deepen understanding of the options Zejula (niraparib) and Jemperli (dostarlimab) bring in treating ovarian and endometrial cancers in certain patients

GlaxoSmithKline (GSK) plc will present new findings in support of advancing treatment for certain gynaecologic cancers, including data evaluating Zejula (niraparib) and Jemperli (dostarlimab) at the upcoming Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer. The meeting will take place in Phoenix, Arizona, and virtually from 18-21 March 2022. The presentations demonstrate GSK's commitment to improving outcomes for patients with gynaecologic cancers through research programmes that identify and address high unmet patient needs.

Hesham Abdullah, Global Head of Oncology Development, GSK said:

> The data we're presenting at SGO will provide the research community with deeper insights about Zejula and Jemperli. We will also share data that furthers our understanding of ovarian and endometrial cancers, and real-world data that sheds light on potential gaps in the care of patients with gynaecologic cancer that need to be addressed.

Exploring optimal use of PARP inhibition maintenance therapy in ovarian cancer

Research being presented at SGO reinforces the role of first-line

maintenance therapy with poly (ADP-ribose) polymerase (PARP) inhibitors in helping to optimise treatment outcomes for patients living with advanced ovarian cancer. This data contributes to the understanding of niraparib in the maintenance treatment of ovarian cancer.

Key oral presentations include:

- OVARIO (oral presentation, ID #39): an oral plenary presentation featuring an updated analysis from this phase II study evaluating niraparib in combination with bevacizumab as first-line maintenance therapy in patients with ovarian cancer following platinum-based chemotherapy and bevacizumab.

- ROYAL (oral presentation, ID #28): an oral plenary presentation featuring a real-world evidence study examining the evolution of the ovarian cancer treatment paradigm in the US and Europe from 2017 to 2020. The findings may help us better understand the treatment paradigm of ovarian cancer and identify remaining unmet needs.

In addition, Zai Lab (a GSK partner) will present a late-breaking oral presentation of the phase III PRIME study (late-breaking oral presentation, ID #5), featuring data evaluating niraparib (independently manufactured by Zai Lab) in Chinese patients with newly diagnosed advanced ovarian cancer using an individualized starting dose.

As part of GSK’s ongoing commitment to the ovarian cancer community, additional real-world studies assessing unmet needs will also be presented, including a study evaluating trends in first-line maintenance treatment use in patients with newly diagnosed advanced ovarian cancer, a study evaluating outcomes in patients with recurrent ovarian cancer who received niraparib as second-line maintenance therapy, and a study that assessed trends in niraparib starting dose as first-line maintenance therapy in patients with newly diagnosed advanced ovarian cancer.

Zejula is a once-daily oral monotherapy maintenance treatment approved for women with first-line platinum-responsive (complete or partial response) advanced ovarian cancer regardless of biomarker status in the US and the European Union (EU).

Advancing standard of care treatment in endometrial cancer

Key dostarlimab presentations at SGO include:

- GARNET trial subgroup (poster presentation, ID #210): a post-hoc analysis from the GARNET trial evaluating the antitumour activity and safety of dostarlimab therapy in patients with endometrial cancer by age subgroups. This analysis will provide insights on outcomes in an older endometrial cancer patient population, potentially helping to inform treatment decisions.

- Dostarlimab indirect treatment comparison (poster presentation, ID #216): an analysis comparing the clinical effectiveness of dostarlimab with doxorubicin in the treatment of advanced or recurrent endometrial cancer, which may help further contextualize how dostarlimab fits in the recurrent or advanced dMMR endometrial cancer treatment landscape.

The GARNET trial was the basis for the US and EU regulatory approvals of Jemperli, a programmed cell death receptor-1 (PD-1) blocking antibody.

Jemperli is the first anti-PD-1 monotherapy approved for endometrial cancer in the EU and received a conditional approval in April 2021 for the treatment of women with mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum-containing regimen. The treatment also received accelerated approval based on tumour response rate and durability of response in the US for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, who have progressed on or following prior treatment with a platinum-containing regimen. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Full list of GSK’s presentations at SGO for niraparib and ovarian cancer:

| Abstract Name | Presenter | Presentation Details |

| Evolution of the Ovarian Cancer Treatment Paradigm, Including Maintenance Treatment, in the US and Europe: A Real-World Chart Review Analysis (2017–2020)| K. Moore | Oral Presentation, ID #28 |

| OVARIO, A Phase II Study of Niraparib + Bevacizumab in Advanced Ovarian Cancer Following Front-Line Platinum-Based Chemotherapy with Bevacizumab: Updated Analysis| M. Hardesty | Oral Presentation, ID #39 |

| Poly (adenosine diphosphate [ADP]-ribose) Polymerase Inhibitor First-Line Maintenance Among Patients with Newly Diagnosed Advanced Ovarian Cancer in a Real-World Database| J. Liu | Poster Presentation, ID #351 |

| Real-World Clinical Outcomes with Poly (adenosine diphosphate [ADP]-ribose) Polymerase Inhibitors as Second-Line Maintenance Therapy in Patients with Recurrent Ovarian Cancer in the United States| U. Matulonis | Poster Presentation, ID #353 |

| Starting Dose of Niraparib as First-Line Maintenance Among Patients with Newly Diagnosed Advanced Ovarian Cancer in a Real-World Database| J. Liu | Poster Presentation, ID #352 |

Full list of GSK's presentations at SGO for dostarlimab and endometrial cancer:

| Abstract Name | Presenter | Presentation Details |

| Antitumor Activity and Safety of Dostarlimab Therapy in Patients with Endometrial Cancer by Age Subgroups: A Post-hoc Analysis from the GARNET Trial| A. Oaknin | Poster Presentation, ID #210 |

| The Comparative Clinical Effectiveness of Dostarlimab Versus Doxorubicin in the Treatment of Advanced/Recurrent Endometrial Cancer| C. Mathews | Poster Presentation, ID #216 |

| Patient Characteristics and Treatment Patterns in Patients With Advanced or Recurrent Endometrial Cancer in Europe: A Real-World Study| Q. Shen | Poster Presentation, ID #348 |

Ovarian cancer is the 8th most common cancer in women worldwide. Despite high response rates to platinum-based chemotherapy in the front-line setting, approximately 85% of patients will experience disease recurrence. Once the disease recurs, it is rarely curable, with decreasing time intervals to each subsequent recurrence.

Endometrial cancer is found in the inner lining of the uterus, known as

the endometrium. It is the most common gynaecologic cancer in the US and second most common gynaecologic cancer globally. Approximately 15-20% of women with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.

Indications and Important US Safety Information for ZEJULA (niraparib)

- for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

- a deleterious or suspected deleterious BRCA mutation, or

- genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for ZEJULA.

Important Safety Information

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in 15 patients (0.8%) out of 1785 patients treated with ZEJULA monotherapy in clinical trials. The duration of therapy in patients who developed secondary MDS/cancer therapy-related AML varied from 0.5 months to 4.9 years. These patients had received prior chemotherapy with platinum agents and/or other DNA-damaging agents including radiotherapy. Discontinue ZEJULA if MDS/AML is confirmed.

Hematologic adverse reactions (thrombocytopenia, anemia,

neutropenia, and/or pancytopenia) have been reported in patients receiving ZEJULA. The overall incidence of Grade ≥3 thrombocytopenia, anemia and neutropenia were reported, respectively, in 39%, 31%, and 21% of patients receiving ZEJULA in PRIMA; 29%, 25%, and 20% of patients receiving ZEJULA in NOVA; and 28%, 27%, and 13% of patients receiving ZEJULA in QUADRA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients in PRIMA; 3%, 1%, and 2% of patients in NOVA; and 4%, 2%, and 1% of patients in QUADRA. In patients who were administered a starting dose of ZEJULA based on baseline weight or platelet count in PRIMA, Grade ≥3 thrombocytopenia, anemia and neutropenia were reported, respectively, in 22%, 23%, and 15% of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 3%, 3%, and 2% of patients. Do not start ZEJULA until patients have recovered from hematological toxicity caused by prior chemotherapy (≤Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months, and periodically thereafter. If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA, and refer the patient to a hematologist for further investigations.

Hypertension and hypertensive crisis have been reported in patients receiving ZEJULA. Grade 3-4 hypertension occurred in 6% of patients receiving ZEJULA vs 1% of patients receiving placebo in PRIMA, with no reported discontinuations. Grade 3-4 hypertension occurred in 9% of patients receiving ZEJULA vs 2% of patients receiving placebo in NOVA, with discontinuation occurring in

Posterior reversible encephalopathy syndrome (PRES) occurred in 0.1% of 2,165 patients treated with ZEJULA in clinical trials and has also been described in postmarketing reports. Monitor all patients for signs and symptoms of PRES, which include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. Diagnosis requires confirmation by brain imaging. If suspected, promptly discontinue ZEJULA and administer appropriate treatment. The safety of reinitiating ZEJULA is unknown.

Embryo-Fetal Toxicity and Lactation: Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective

contraception during treatment and for 6 months after receiving their final dose of ZEJULA. Because of the potential for serious adverse reactions from ZEJULA in breastfed infants, advise lactating women not to breastfeed during treatment with ZEJULA and for 1 month after receiving the final dose.

Allergic reactions to FD&C Yellow No. 5 (tartrazine): ZEJULA capsules contain FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

First-line Maintenance Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (64%), nausea (57%), fatigue (51%), neutropenia (42%), constipation (40%), musculoskeletal pain (39%), leukopenia (28%), headache (26%), insomnia (25%), vomiting (22%), dyspnea (22%), decreased appetite (19%), dizziness (19%), cough (18%), hypertension (18%), AST/ALT elevation (14%), and acute kidney injury (12%).

Common lab abnormalities (Grades 1-4) in ≥25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (87%), decreased platelets (74%), decreased leukocytes (71%), increased glucose (66%), decreased neutrophils (66%), decreased lymphocytes (51%), increased alkaline phosphatase (46%), increased creatinine (40%), decreased magnesium (36%), increased AST (35%) and increased ALT (29%).

Maintenance Recurrent Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in NOVA were nausea (74%), thrombocytopenia (61%), fatigue/asthenia (57%), anemia (50%), constipation (40%), vomiting (34%), neutropenia (30%), insomnia (27%), headache (26%), decreased appetite (25%), nasopharyngitis (23%), rash (21%), hypertension (20%), dyspnea (20%), mucositis/stomatitis (20%), dizziness (18%), back pain (18%), dyspepsia (18%), leukopenia (17%), cough (16%), urinary tract infection (13%), anxiety (11%), dry mouth (10%), AST/ALT elevation (10%), dysgeusia (10%), palpitations (10%).

Common lab abnormalities (Grades 1-4) in ≥25% of patients who received ZEJULA in NOVA included: decrease in hemoglobin (85%), decrease in platelet count (72%), decrease in white blood cell count (66%), decrease in absolute neutrophil count (53%), increase in AST (36%) and increase in ALT (28%).

Treatment of Advanced HRD+ Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received ZEJULA in QUADRA were nausea (67%), fatigue (56%), thrombocytopenia (52%), anemia (51%), vomiting (44%), constipation (36%), abdominal pain (34%), musculoskeletal pain (29%), decreased appetite (27%), dyspnea (22%), insomnia (21%), neutropenia (20%), headache (19%), diarrhea (17%), acute kidney injury (17%), urinary tract infection (15%), hypertension (14%), cough (13%), dizziness (11%), AST/ALT elevation (11%), blood alkaline phosphatase increased (11%).

Common lab abnormalities (Grades 1-4) in ≥25% of patients who received ZEJULA in QUADRA included: decreased hemoglobin (83%), increased glucose (66%), decreased platelets (60%), decreased lymphocytes (57%), decreased leukocytes (53%), decreased magnesium (46%), increased alkaline phosphatase (40%), increased gamma glutamyl transferase (40%), increased creatinine (36%), decreased sodium (34%), decreased neutrophils (34%), increased aspartate aminotransferase (29%), and decreased albumin (27%).

Please see full Prescribing Information

Indications and Important US Safety Information for JEMPERLI (dostarlimab-gxly)

JEMPERLI is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:

- endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen, or

- solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on tumor response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.

- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Pneumonitis occurred in 1.4% (7/515) of patients, including Grade 2 (1.2%) and Grade 3 (0.2%) pneumonitis.

- Colitis occurred in 1.4% (7/515) of patients, including Grade 2 (0.8%) and Grade 3 (0.6%) adverse reactions. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis. In such cases, consider repeating infectious workup to exclude alternative etiologies.

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.2% (1/515) of patients.

Immune-Mediated Endocrinopathies

- Adrenal insufficiency occurred in 1.4% (7/515) of patients, including Grade 2 (0.8%) and Grade 3 (0.6%). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

- JEMPERLI can cause immune-mediated hypophysitis. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

- Thyroiditis occurred in 0.4% (2/515) of patients; both were Grade 2. Hypothyroidism occurred in 7.2% (37/515) of patients, all of which were Grade 2. Hyperthyroidism occurred in 1.9% (10/515) of patients, including Grade 2 (1.7%) and Grade 3 (0.2%). Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis

- JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Nephritis occurred in 0.4% (2/515) of patients; both were Grade 2.

Immune-Mediated Dermatologic Adverse Reactions

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS),

toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in

- Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

- Cardiac/Vascular: Myocarditis, pericarditis, vasculitis

- Ocular: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur

- Gastrointestinal: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis

- Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

- Endocrine: Hypoparathyroidism

- Other (Hematologic/Immune): Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection

Infusion-Related Reactions

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/515) of patients receiving JEMPERLI. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or

permanently discontinue JEMPERLI based on severity of reaction.

Complications of Allogeneic HSCT

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody, which may occur despite intervening therapy. Monitor patients closely for transplant-related complications and intervene promptly.

Embryo-Fetal Toxicity and Lactation

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in a breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

The most common adverse reactions (≥20%) in patients with dMMR EC were fatigue/asthenia, nausea, diarrhea, anemia, and constipation. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased sodium, decreased leukocytes, decreased albumin, increased creatinine, increased alkaline phosphatase, and increased alanine aminotransferase.

Please see full Prescribing Information

GSK is focused on maximising patient survival through transformational medicines. GSK's pipeline is focused on immuno-oncology, cell therapy, 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, antibody-drug conjugates and cell therapy, either alone or in combination.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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 in the Company's Annual Report on Form 20-F for 2021 and any impacts of the COVID-19 pandemic.

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