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New data at ASCO showcases the transformational potential of GSK's oncology portfolio

- DREAMM-8 results for belantamab mafodotin in multiple myeloma featured in a late-breaking presentation and ASCO's Press Program
- Updated results from a supported collaborative study for *Jemperli* (dostarlimab-gxly) in locally advanced mismatch repair deficient rectal cancer

GSK plc (LSE/NYSE: GSK) today announced that findings across its oncology portfolio will be presented in 25 abstracts at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting (31 May - 4 June) in Chicago, IL. The presentations support GSK's ongoing focus and commitment to advance care in blood cancers, gynecologic cancers and certain solid tumors through novel approaches.

DREAMM program updates

Pivotal data will be shared from the DREAMM-8 and DREAMM-7 phase III trials showing the potential of belantamab mafodotin in combination versus standard of care in multiple myeloma at or after first relapse, including:

- Results from the DREAMM-8 trial evaluating belantamab mafodotin in combination with pomalidomide and dexamethasone (PomDex) versus bortezomib combined with PomDex. This data was selected for inclusion in ASCO press program (ASCO abstract #LBA105).
- Subgroup analyses from the DREAMM-7 trial evaluating belantamab mafodotin plus bortezomib and dexamethasone (BorDex) versus daratumumab plus BorDex (ASCO abstract #7503).
- Encore presentation (ASCO abstract #7543) of the [primary results from DREAMM-7](#), originally featured in the ASCO Plenary Series on February 6, 2024.

Collaborations to improve patient care

Encouraging new data will be presented from GSK's portfolio of supported collaborative studies and alliances that could transform outcomes for patients with cancer:

- Updated results for dostarlimab-gxly in locally advanced mismatch repair deficient (dMMR) rectal cancer will be presented in a late-breaking rapid oral presentation (ASCO abstract #LBA3512), a supported collaborative study with Memorial Sloan Kettering Cancer Center. This follows data presented at the 2022 ASCO and 2023 Japanese Society of Medical Oncology Annual Meetings.
- Hansoh Pharma will deliver an oral presentation on their phase II study of HS-20093 in Chinese patients with relapsed or refractory osteosarcoma (ASCO abstract #11507). Earlier this year, GSK obtained exclusive worldwide rights (excluding China's mainland, Hong Kong, Macau and Taiwan) to progress clinical development and commercialization of HS-20093.
- Updated results will be presented from a phase 0/II trial of niraparib in patients with newly diagnosed MGMT-unmethylated glioblastoma (ASCO abstract #2002), a supported collaborative study sponsored by the Ivy Brain Tumor Center. Treatment with niraparib achieved a median overall survival of 20.3 months, compared to a historical control of 12.7 months.^{1,2} The safety profile was consistent with what has been previously reported in this study. Based on these results, a phase III clinical trial of niraparib versus standard of care has been accelerated, supported by GSK.



Full list of GSK's presentations at ASCO:

Belantamab Mafodotin

Abstract Name	Presenter	Presentation details
Results from the randomized Phase III DREAMM-8 study of belantamab mafodotin (belamaf) plus pomalidomide and dexamethasone (BPd) versus pomalidomide plus bortezomib and dexamethasone (PVd) in relapsed/refractory multiple myeloma (RRMM)	S. Trudel	Clinical Science Symposium, #LBA105
Results from the randomized phase III DREAMM-7 study of belamaf + bortezomib, and dexamethasone (BVd) vs daratumumab, bortezomib, and dexamethasone (DVd) in RRMM	MV. Mateos	Oral, Education session, Presentation 4
DREAMM-7 update: Subgroup analyses from a phase 3 trial of belantamab mafodotin (belamaf) + bortezomib and dexamethasone (BVd) vs daratumumab, bortezomib, and dexamethasone (DVd) in relapsed/refractory multiple myeloma (RRMM)	MV. Mateos	Oral abstract session, #7503
Patient-reported outcomes (PROs) from the DREAMM-7 randomized phase 3 study comparing belantamab mafodotin, bortezomib, dexamethasone (BVd) vs daratumumab, bortezomib and dexamethasone (DVd) in patients with relapsed/refractory multiple myeloma (RRMM)	V. Hungria	Poster session, #7543

Dostarlimab-gxly

Abstract Name	Presenter	Presentation Details
Post hoc analysis of progression-free survival (PFS) and overall survival (OS) by mechanism of mismatch repair (MMR) protein loss in patients with endometrial cancer treated with dostarlimab plus chemotherapy in the RUBY trial	M. Mirza	Poster session, #5606
Time course of adverse events in primary advanced or recurrent endometrial cancer treated with dostarlimab plus chemotherapy in the ENGOT-EN-6-NSGO/GOG-3031/RUBY trial	E. Lokich	Poster session, #5607

Niraparib

Abstract Name	Presenter	Presentation Details
The BEV1L study: Do real-world outcomes associated with the addition of bevacizumab to first-line chemotherapy in patients with ovarian cancer reinforce clinical trial findings?	L. Duska	Poster session, #5563
First-in-human, phase 1/2 study of GSK4524101, an oral DNA polymerase theta inhibitor (POLQi), alone or combined with the poly(ADP-ribose) polymerase	V. Samnotra	Poster session, #TPS3174

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(PARP) inhibitor (PARPi) niraparib in adults with solid tumors		
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Momelotinib

Abstract Name	Presenter	Presentation Details
Long-term survival adjusted for treatment crossover in patients (pts) with myelofibrosis (MF) treated with momelotinib (MMB) vs. danazol (DAN) in the MOMENTUM trial	R. Mesa	Poster session, #6571
Association between hemoglobin (Hb) improvement and patient-reported outcomes (PROs) in patients (pts) with myelofibrosis (MF) patients and anemia: Post hoc pooled analysis of momelotinib (MMB) phase 3 trials	T. LeBlanc	Poster session, #6574
Patient (pt) interview-based content validation of the Myelofibrosis Symptom Assessment Form version 4.0 (MFSAF v4.0)	A. Cardellino	Online publication, #e23106
Patient (pt) experience with and perceptions around transfusion-dependent (TD) and transfusion-independent (TI) myelofibrosis (MF): A qualitative interview study	A. Cardellino	Online publication, #e23110

Cobolimab

Abstract Name	Presenter	Presentation Details
Real-world treatment patterns and outcomes in US patients (pts) with advanced non-small cell lung cancer (NSCLC) after platinum-based chemotherapy (PBC) and anti-PD-(L)1 treatment	V. Velcheti	Poster session, #8627

Full list of investigator-initiated studies and supported collaborative studies at ASCO:

Abstract Name	Presenter	Presentation Details
Durable complete responses to PD-1 blockade alone in mismatch repair deficient locally advanced rectal cancer	A. Cercek	Rapid oral abstract session, #LBA3512
Niraparib and dostarlimab efficacy in patients with platinum-sensitive relapsed mesothelioma: MIST5, a phase IIa clinical trial	DA. Fennell	Rapid oral abstract session, #8017
Niraparib efficacy in patients with newly-diagnosed glioblastoma: Clinical readout of a phase 0/2 "trigger" trial	N. Sanai	Oral abstract session, #2002
Evaluation of a novel method to guide belantamab mafodotin dosing in multiple myeloma based on a patient-reported questionnaire	E. Terpos	Poster session, #7530
Open-label, single-arm phase Ib/II study of immune combination therapy with elotuzumab and belantamab mafodotin in patients with relapsed/refractory multiple myeloma	N. Neparidze	Poster session, #7559
A three-arm randomized phase II study of dostarlimab alone or with bevacizumab versus nonplatinum chemotherapy in recurrent	JY. Lee	Poster session, #TPS5627



gynecological clear cell carcinoma: DOVE (APGOT-OV7/ENGOT-ov80 study)		
TTCC-2022-01: Niraparib and dostarlimab in locally-advanced head and neck squamous cell carcinoma treated with (chemo) radiotherapy (RADIANT)	M. Oliva	Poster session, #TPS6125
Efficacy and safety of GPRC5D-based monotherapies for relapsed/refractory multiple myeloma: A systematic review and meta-analysis	A. Shrestha	Online publication, #e19503
Real-world analysis of belantamab mafodotin (belamaf): Care patterns in relapsed/refractory multiple myeloma	M. Patel	Online publication, #e19507
Age-related differences in information seeking behaviors of patients with multiple myeloma	JM. Ahlstrom	Online publication, #e19523
Exploring gender-based decision-making differences among patients with relapsed/refractory multiple myeloma	M. Arnett	Online publication, #e19524
The role of patient-driven education in decision-making for relapsed/refractory multiple myeloma	JR. Hydren	Online publication, #e19532

About multiple myeloma

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.^{3,4} There are approximately 176,000 new cases of multiple myeloma diagnosed globally each year.⁵ Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.⁶

About dMMR/MSI-H rectal cancer

Rectal cancer is a form of cancer that starts in the rectum, the final section of the large intestine, and is often categorized as part of a group of cancers called colorectal cancer.⁷ Colorectal cancer is the third most commonly diagnosed cancer in the world.⁸ In the US, it is estimated that approximately 46,220 individuals are diagnosed annually with rectal cancer.⁹ Approximately 5-10% of all rectal cancers are mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H), meaning that they contain abnormalities that affect the proper repair of DNA when copied in a cell.¹⁰ Mismatch repair-deficient status is a biomarker that has been shown to predict response to immune checkpoint blockade with PD-1 therapy.^{11,12} Tumors with this biomarker are most commonly found in endometrial, colorectal and other gastrointestinal cancers but may also be found in other solid tumors.¹³⁻¹⁵

About glioblastoma

Glioblastoma is a type of cancer that starts as a growth of cells in the brain or spinal cord. It grows quickly and can invade and destroy healthy tissue.¹⁶ It accounts for more than half of all primary malignant brain tumors and is one of the most complex and treatment-resistant cancers, resulting in poor patient outcomes.¹⁷ Survival rates and mortality statistics for glioblastoma have been virtually unchanged for decades, highlighting the need to investigate new treatment options.¹⁷

About belantamab mafodotin

Belantamab mafodotin is an investigational antibody-drug conjugate comprising a humanized B-cell maturation antigen monoclonal antibody conjugated to the cytotoxic agent auristatin F via a non-cleavable linker. The drug linker technology is licensed from Seagen Inc.; the monoclonal antibody is produced using POTELLIGENT Technology licensed from BioWa Inc., a member of the Kyowa Kirin Group.

About Jemperli (dostarlimab-gxly)

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-L2.¹⁹

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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, commercialization, and manufacturing of *Jemperli*, and cobolimab (GSK4069889), a TIM-3 Antagonist.

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

- JEMPERLI, in combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with dMMR recurrent or advanced:
 - EC, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation, 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. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication 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 2.3% (14/605) of patients, including Grade 2 (1.3%), Grade 3 (0.8%), and Grade 4 (0.2%) pneumonitis.

Immune-Mediated Colitis

- Colitis occurred in 1.3% (8/605) of patients, including Grade 2 (0.7%) and Grade 3 (0.7%) 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.

Immune-Mediated Hepatitis

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

Immune-Mediated Endocrinopathies

- Adrenal Insufficiency
 - Adrenal insufficiency occurred in 1.2% (7/605) of patients, including Grade 2 (0.5%) and Grade 3 (0.7%). 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.

- Hypophysitis
 - JEMPERLI can cause immune-mediated hypophysitis. Grade 3 hypophysitis occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypophysitis occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Thyroid Disorders
 - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (28/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypothyroidism occurred in 8% (46/605) of patients receiving JEMPERLI as a single agent. Hyperthyroidism occurred in 3.3% (8/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel, including Grade 2 (2.9%) and Grade 3 (0.4%). Hyperthyroidism occurred in 2.3% (14/605) of patients receiving JEMPERLI as a single agent, including Grade 2 (2.1%) and Grade 3 (0.2%). Initiate thyroid 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. Grade 3 type 1 diabetes mellitus occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 3 type 1 diabetes mellitus occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. 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. Grade 2 nephritis, including tubulointerstitial nephritis, occurred in 0.5% (3/605) of patients.

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 <1% of the 605 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
 - *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré 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

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lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) 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% (1/605) 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.

Common Adverse Reactions

The most common adverse reactions ($\geq 20\%$) in patients with dMMR/MSI-H EC who received JEMPERLI in combination with carboplatin and paclitaxel were rash, diarrhea, hypothyroidism, and hypertension. The most common Grade 3 or 4 laboratory abnormalities ($\geq 10\%$) were decreased neutrophils, decreased hemoglobin, decreased white blood cell count, decreased lymphocytes, increased glucose, decreased sodium, and decreased platelets.

The most common adverse reactions ($\geq 20\%$) in patients with dMMR EC who received JEMPERLI as a single agent were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash. The most common Grade 3 or 4 laboratory abnormalities ($> 2\%$) were decreased lymphocytes, decreased sodium, increased alanine aminotransferase, increased creatinine, decreased neutrophils, decreased albumin, and increased alkaline phosphatase.

The most common adverse reactions ($\geq 20\%$) in patients with dMMR solid tumors who received JEMPERLI as a single agent were fatigue/asthenia, anemia, diarrhea, and nausea. The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

Please see the full [US Prescribing Information for JEMPERLI](#).

About Zejula (niraparib)

Zejula is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor.

INDICATION

ZEJULA is indicated:

- for first-line 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

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- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to 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 cases with a fatal outcome, have been reported in patients who received ZEJULA. In PRIMA, MDS/AML occurred in 6 out of 484 (1.2%) patients treated with ZEJULA, and in 3 out of 244 (1.2%) patients treated with placebo. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 3.7 months to 2.5 years. In NOVA₁, of patients within the *gBRCA*mut cohort, MDS/AML occurred in 10 out of 136 (7%) patients treated with ZEJULA and in 2 out of 65 (3%) patients treated with placebo. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 3.6 months to 5.9 years. All patients who developed secondary MDS/cancer therapy-related AML had received previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy. For suspected MDS/AML or prolonged hematological toxicities, refer the patient to a hematologist for further evaluation. 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 and 29%, 25%, and 20% of patients receiving ZEJULA in NOVA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients in PRIMA and 3%, 1%, and 2% of patients in NOVA. 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 (\leq 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 $<1\%$ of patients. Monitor blood pressure and heart rate at least weekly for the first two months, then monthly for the first year, and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Manage hypertension with antihypertensive medications and adjustment of the ZEJULA dose if necessary.

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 last dose.

First-line Maintenance Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in $\geq 10\%$ 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%),

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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 $\geq 25\%$ 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 Germline *BRCA*-mutated Ovarian Cancer

Most common adverse reactions (Grades 1-4) in $\geq 10\%$ of patients who received ZEJULA in NOVA *gBRCA*mut Cohort were nausea (77%), thrombocytopenia (71%), fatigue (61%), anemia (52%), vomiting (40%), constipation (38%), headache (35%), neutropenia (31%), decreased appetite (22%), hypertension (21%), insomnia (18%), dizziness (18%), dyspnea (17%), dyspepsia (17%), back pain (16%), cough (16%), nasopharyngitis (13%), dry mouth (13%), dysgeusia (13%), urinary tract infection (11%), rash (10%), and anxiety (10%).

Common lab abnormalities (Grades 1-4) in $\geq 25\%$ of patients who received ZEJULA in NOVA *gBRCA*mut Cohort included: decrease in hemoglobin (85%), decrease in platelet count (81%), decrease in white blood cell count (71%), decrease in absolute neutrophil count (56%), increase in AST (35%), and increase in ALT (25%).

Please see the [US Prescribing Information for ZEJULA](#).

About *Ojjaara* (momelotinib)

Ojjaara has a differentiated mechanism of action, with inhibitory ability along three key signalling pathways: Janus kinase (JAK) 1, JAK2, and activin A receptor, type I (ACVR1).^{2,6,11,13} Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly.^{2,6,23} Additionally, inhibition of ACVR1 leads to a decrease in circulating hepcidin, which is elevated in myelofibrosis and contributes to anemia.^{2,6,22,23}

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Hepatitis B Reactivation

- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of OJJAARA on viral replication in patients with chronic HBV infection is unknown. In patients with HBV infections, check hepatitis B serologies prior to starting OJJAARA. If HBsAg and/or anti-HBc antibody is positive, consider consultation with a hepatologist regarding monitoring for reactivation versus prophylactic hepatitis B therapy. Patients with chronic HBV infection who receive OJJAARA should have their chronic HBV infection treated and monitored according to clinical HBV guidelines.

Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than $50 \times 10^9/L$, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than $50 \times 10^9/L$.
- Severe neutropenia, absolute neutrophil count (ANC) less than $0.5 \times 10^9/L$, was observed in 2% of patients treated with OJJAARA.
- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.



Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.
- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.
- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.

Major Adverse Cardiovascular Events (MACE)

- Another JAK inhibitor increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke [compared with those treated with tumor necrosis factor (TNF) blockers] in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients receiving OJJAARA of the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis

- Another JAK inhibitor increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Evaluate patients with symptoms of thrombosis and treat appropriately.

Malignancies

- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Adverse Reactions

- The most common adverse reactions ($\geq 20\%$ in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications.

Breast Cancer Resistance Protein (BCRP) Substrates

- Momelotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates.

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Pregnancy

- Available data in pregnant women are insufficient. OJJAARA should only be used during pregnancy if the expected benefits to the mother outweigh the potential risks to the fetus.

Lactation

- It is not known whether OJJAARA is excreted in human milk. Because of the potential for serious adverse reactions in a breastfed child, patients should not breastfeed during treatment with OJJAARA, and for at least 1 week after the last dose of OJJAARA.

Females and Males of Reproductive Potential

- Advise females of reproductive potential who are not pregnant to use highly effective contraception during therapy and for at least 1 week after the last dose of OJJAARA.

Hepatic Impairment

- Mometinib exposure increased with severe hepatic impairment (Child-Pugh C). The recommended starting dose of OJJAARA in patients with severe hepatic impairment (Child-Pugh C) is 150 mg orally once daily. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B).

Please see full [Prescribing Information](#), including Patient Information, for OJJAARA.

GSK in oncology

Oncology is an emerging therapeutic area for GSK where we are committed to maximizing patient survival with a current focus on hematologic malignancies, gynecologic cancers, and other solid tumors through breakthroughs in immuno-oncology and tumor-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 us.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 Q1 Results for 2024.

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