Press release

For media and investors only

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GSK to showcase long-term outcomes and pipeline expansion with latest oncology research at ASCO and EHA

- Promising phase Ib results for velzatinib* (IDRX-42) support accelerating start of phase III trial in 1L gastrointestinal stromal tumors (GIST)
- New *Blenrep* (belantamab mafodotin-blmf) results will highlight potential for long-term efficacy in relapsed or refractory multiple myeloma and meaningful activity in newly diagnosed patients
- Modelling data predict cure rate with *Jemperli* (dostarlimab-gxly) plus chemotherapy in dMMR/MSI-H primary advanced or recurrent endometrial cancer
- New analyses will show *Ojjaara* (momelotinib) delivers benefit across patient subgroups including when switching from ruxolitinib

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GSK plc (LSE/NYSE: GSK) will present new data from its expanding oncology portfolio and pipeline at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting (May 29 - June 2) in Chicago, IL and the 31st European Hematology Association (EHA) Congress (June 11 - 14) in Stockholm, Sweden. These findings demonstrate long-term outcomes for current therapies and pipeline expansion into additional tumor types and earlier treatment lines to advance practice-changing medicines for people with cancer.

First results for velzatinib in first-line (1L) advanced gastrointestinal stromal tumors (GIST) will show promising activity and tolerability across KIT mutations. These data have accelerated initiation of the StrateGIST Frontline phase III clinical trial given the need for therapies in 1L that broadly inhibit clinically relevant KIT variants, a key driver of relapse today.

- Data for velzatinib across clinically relevant KIT mutations in all lines, including 1L and second-line (2L) advanced GIST, will show encouraging anti-tumor activity and tolerability supporting the potential for a differentiated clinical profile (ASCO oral presentation abstract #11501).
- Analyses of velzatinib will show broad activity and substantial circulating tumor DNA (ctDNA) clearance of clinically meaningful KIT mutations and inhibition of GIST tumor cells (ASCO rapid oral presentation abstract #11520).

New DREAMM clinical trial program data will show durable benefit with belantamab mafodotin-blmf combinations in relapsed or refractory multiple myeloma (RRMM) and potential in newly diagnosed multiple myeloma

- Four-year results from DREAMM-7 will show long-term efficacy, including overall survival, depth of response and health-related quality of life, reinforcing belantamab mafodotin-blmf with bortezomib and dexamethasone as a potential new standard of care in RRMM (EHA abstract #PS1862).
- DREAMM-8 long-term responder and sustained minimal residual disease negativity analyses will show depth and durability of response for patients treated with belantamab mafodotin-blmf in combination with pomalidomide and dexamethasone in RRMM (ASCO abstract #7565 and rapid oral presentation abstract #7515).
- In transplant-ineligible newly diagnosed multiple myeloma patients, final DREAMM-9 analysis will provide clinical evidence of meaningful activity with an optimized induction/maintenance dosing strategy of belantamab mafodotin-blmf (ASCO oral presentation abstract #7503).

Latest modelling data will predict the cure rate with dostarlimab-gxly plus chemotherapy in dMMR/MSI-H primary advanced or recurrent endometrial cancer, supporting patient care

- New long-term analyses from the phase III RUBY trial will reinforce the sustained benefit of dostarlimab-gxly plus chemotherapy in patients with mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) primary advanced or recurrent endometrial cancer. Building from these results, new modelling analyses predict the proportion of patients who may be considered “cured”—defined as those who survive their disease and no

longer experience disease-related mortality. These data complement traditional clinical trial measures, such as progression-free and overall survival, to support clinicians in advising their patients on treatment options and potential outcomes (ASCO oral presentation abstract #5501).

New analyses will show momelotinib can deliver symptom control across myelofibrosis patient subgroups and when switching from ruxolitinib

- Post-hoc analyses from SIMPLIFY-1 and MOMENTUM will further build evidence for momelotinib across patient risk profiles in myelofibrosis, demonstrating consistent spleen, symptom and anemia responses. Data will show earlier initiation of treatment before progression may be associated with better outcomes, underscoring the importance of initiating treatment before progression (EHA abstract #PS1995).
- New analyses from SIMPLIFY-1 and SIMPLIFY-2 will show that most patients in the trials could transition directly from ruxolitinib to momelotinib without acute symptom worsening. Symptoms remained stable or improved in the majority of patients. These data address a key challenge in treatment sequencing (EHA abstract #PS2001).

Full list of GSK's presentations at ASCO:

Belantamab mafodotin-blmf

Abstract Name	Presenter	Presentation details
Durable clinical benefit with B-cell maturation antigen (BCMA) – directed therapy, belantamab mafodotin-blmf plus pomalidomide and dexamethasone (BPd) in relapsed/refractory multiple myeloma (RRMM): DREAMM-8 long-term responder (LTR) analysis	M. Dimopoulos	Abstract #7565 Poster Session
Long-term outcomes with sustained minimal residual disease (MRD) negativity in belantamab mafodotin-blmf-treated patients (pts) with relapsed/refractory multiple myeloma (RRMM): An update from DREAMM-8	M. Dimopoulos	Abstract #7515 Rapid Oral Abstract Session
PFS2 outcomes by prior therapy from DREAMM-8: A phase 3 study assessing belantamab mafodotin-blmf (belamaf), pomalidomide, and dexamethasone (BPd) vs pomalidomide, bortezomib, and dexamethasone (PVd) in patients (pts) with relapsed/refractory multiple myeloma (RRMM)	G. Cengiz-Seval	Abstract #7566 Poster Session
Matching-adjusted indirect comparison (MAIC) for belantamab mafodotin-blmf (belamaf) with pomalidomide and dexamethasone (BPd) vs daratumumab with pomalidomide and dexamethasone (DPd) in relapsed/refractory multiple myeloma (RRMM)	J. Richter	Abstract #e19574 Online Publication
Comparative efficacy of belantamab mafodotin-blmf plus bortezomib and dexamethasone (BVd) vs standard of care in patients with relapsed/refractory multiple myeloma (RRMM)	J. Richter	Abstract #7568 Poster Session
DREAMM-9 final analysis: Belantamab mafodotin-blmf (belamaf), bortezomib, lenalidomide, and dexamethasone (BVRd) for transplant-ineligible (TI) newly diagnosed multiple myeloma (NDMM)	S. Usmani	Abstract #7503 Oral Abstract Session
Gaps in access to chimeric antigen receptor T-cell (CAR-T) therapy post leukapheresis: Waiting time and post-leukapheresis treatment patterns in	S. Ailawadhi	Abstract #7530 Poster Session

relapsed/refractory multiple myeloma (RRMM)– Real-world evidence from U.S. claims		

Dostarlimab-gxly

Abstract Name	Presenter	Presentation details
Long-term survival rates and cure modeling with dostarlimab-gxly plus chemotherapy in mismatch repair deficient/microsatellite instability-high primary advanced or recurrent endometrial cancer in the ENGOT-EN6-NSGO/GOG-3031/RUBY trial	M. Powell	Abstract #5501 Oral Abstract Session
Safety and efficacy of dostarlimab-gxly monotherapy as first-line treatment in programmed cell death-ligand 1-positive recurrent/metastatic head and neck squamous cell carcinoma: Results from a Phase 2 trial	R. Haddad	Abstract #6037 Poster Session

Niraparib

Abstract Name	Presenter	Presentation details
Efficacy prediction for progression-free survival (PFS) and overall survival (OS) by genomic instability score (GIS) cutoffs patients (pts) with advanced ovarian cancer (aOC): Post hoc results from phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial	B. Monk	Abstract #5565 Poster Session
Genomic instability score (GIS) and real-world outcomes in patients (pts) with advanced ovarian cancer (AOC) using a U.S. health database	E. Swisher	Abstract # e17565 Online Publication
Predictors of real-world progression-free survival in patients with epithelial ovarian cancer who received 1LM niraparib: Post-hoc analysis of the 1NSPIRE chart review study	L. Landrum	Abstract #e17556 Online Publication

Velzatinib

Abstract Name	Presenter	Presentation details
Velzatinib (IDRX-42) as 1L or 2L therapy for advanced gastrointestinal stromal tumors (GISTs) by KIT mutation status: A subset analysis of the phase 1/1b StrateGIST 1 study	R. Jones	Abstract #11501 Oral Abstract Session
Efficacy of velzatinib (IDRX-42) in patients with advanced/metastatic GIST by line of therapy and circulating tumor DNA response in the phase 1/1b StrateGIST 1 trial	M. Heinrich	Abstract #11520 Rapid Oral Abstract Session
StrateGIST 3: A randomized, phase 3 study of velzatinib (IDRX-42) versus sunitinib in patients with advanced gastrointestinal stromal tumors after imatinib therapy	S. George	Abstract # TPS11588 Poster Session

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

Abstract Name	Presenter	Presentation details
Belantamab mafodotin-blmf with daratumumab, lenalidomide and dexamethasone in transplant-ineligible, newly diagnosed multiple myeloma patients: Phase 1/2 BelaDRd study	E. Terpos	Abstract #7512 Oral Abstract Session
ISABELA: A phase 2 study of isatuximab, belantamab mafodotin-blmf, pomalidomide, and dexamethasone in relapsed/refractory multiple myeloma	A. Yee	Abstract #7562 Poster Session
Organ preservation strategy using dostarlimab-gxly for dMMR/MSI-H resectable solid tumors with whole-genome based MRD monitoring (D-CURE: EPOC2401)	Y. Matsubara	Abstract # TPS2697 Poster Session
Niraparib and dostarlimab-gxly in locally advanced head and neck squamous cell carcinoma (LA-HNSCC) treated with (chemo)radiotherapy (CRT): Results from the phase IB-II TTCC-2022-01 RADIAN trial	M. Oliva	Abstract #6096 Poster Session
Age-related differences in patient burden in endometrial cancer: Findings from the International EXPRESSION XI/IMPROVE Survey	P. Combe	Abstract #e17622 Online Publication
Gliofocus: A global, open-label, randomized phase 3 study comparing niraparib with temozolomide in newly diagnosed MGMT-unmethylated glioblastoma	Y. Umemura	Abstract #TPS2102 Poster Session
Phase Ib study of momelotinib during and following hematopoietic stem cell transplantation for patients with primary or secondary myelofibrosis	G. Hobbs	Abstract #TPS6607 Poster Session
A phase 2 study to assess the safety and efficacy of bomedemstat (IMG-7289) in combination with momelotinib in patients with myelofibrosis	C. Rinaldi	Abstract # TPS6605 Poster Session
Neoadjuvant DAN-222 plus niraparib in high-risk HER2-negative breast cancer: Results from the I-SPY 2 adaptive platform trial	K. Yeung	Abstract #625 Poster Session
TBCRC 050: A phase 1b/2 trial of niraparib and trastuzumab in HER2-positive metastatic breast cancer (MBC): Efficacy and correlative analyses	E. Stringer-Reasor	Abstract #1056 Poster Session
An observational study to investigate the effectiveness and safety of niraparib maintenance therapy after frontline chemotherapy for Taiwanese patients with advanced ovarian cancer: Interim results	H. Chou	Abstract # e17546 Online Publication
Circulating tumor DNA (ctDNA) from a phase II study of adjuvant dostarlimab-gxly with pelvic radiation in locally advanced, mismatch repair-deficient (MMR-D) endometrial cancer (D-RT Study)	G. Sotolongo	Abstract #5613 Poster Session

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Full list of GSK presentations at EHA:

Belantamab mafodotin-blmf

Abstract Name	Presenter	Presentation details
Overall survival of anti-BCMA therapies: Indirect comparison of belantamab mafodotin-blmf/bortezomib/dexamethasone (BVd) vs teclistamab/daratumumab (tec-dara) in relapsed/refractory multiple myeloma (RRMM)	J. Richter	Abstract #PS1933 Poster Session
The emerging 'transplant deferred' population in newly diagnosed multiple myeloma (NDMM) represents a substantial evidence gap in the novel-agent era	S. Kumar	Abstract #PB3365 Online Publication
Patient characteristics and initial real-world dosing experience with belantamab mafodotin-blmf-based combinations for relapsed/refractory multiple myeloma	E. Zamagni	Abstract #PB3253 Online Publication
Design of the phase 2 ALANIS study: Belantamab mafodotin-blmf in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) in patients with newly diagnosed amyloid light chain amyloidosis	E. Kastritis	Abstract #PB3262 Online Publication
Belantamab mafodotin-blmf, bortezomib, and dexamethasone vs daratumumab, bortezomib, and dexamethasone in relapsed/refractory multiple myeloma: Updated 4-year results of the phase 3 DREAMM-7 trial	V. Hungria	Abstract # PS1862 Poster Session
Belantamab mafodotin-blmf, pomalidomide, and dexamethasone (BPd) demonstrated improved outcomes as second-line therapy vs pomalidomide, bortezomib, and dexamethasone (PVd) in patients with multiple myeloma	M. Beksac	Abstract #PS1877 Poster Session
Development and preliminary content validation of the PROSIM-Q: A patient-reported ocular symptom and impact questionnaire for oncology trials	F. Pompilus	Abstract #PS1938 Poster Session
DREAMM-15: A study assessing the efficacy and safety of extended dosing of belantamab mafodotin-blmf in combination with standard of care therapies in patients with relapses-refractory multiple myeloma	D. Sborov	Abstract #PB3225 Online Publication
Real-world treatment patterns and outcomes of relapsed/refractory multiple myeloma in China: Insights from the NICHE-MM registry (2018–2025)	G. An	Abstract #PB3302 Online Publication
Resource utilization and costs related to the adverse events management of relapsed/refractory multiple myeloma in Brazil: Microcosting from the private healthcare system perspective	S. Tanaka	Abstract #PB4473 Online Publication
Durable clinical benefit with B-cell maturation antigen therapy, belantamab mafodotin-blmf, pomalidomide, and dexamethasone, in relapsed/ refractory multiple myeloma: DREAMM-8 long-term responder analysis	M. Dimopoulos	Abstract #PF764 Poster Session

Long-term outcomes with sustained minimal residual disease (MRD) negativity in belantamab mafodotin-blmf-treated patients (pts) with relapsed/refractory multiple myeloma (RRMM): An update from DREAMM-8	M. Dimopoulos	Abstract #PF792 Poster Session
PFS2 outcomes by prior therapy from DREAMM-8: Belantamab mafodotin-blmf, pomalidomide, and dexamethasone vs pomalidomide, bortezomib, and dexamethasone in patients with relapsed/refractory multiple myeloma	G. Cengiz-Seval	Abstract #PF776 Poster Session
DREAMM-9 final analysis: Belantamab mafodotin-blmf (belamaf), bortezomib, lenalidomide, and dexamethasone (BVRd) for transplant-ineligible (TI) newly diagnosed multiple myeloma (NDMM)	E. Ocio	Abstract #PF762 Poster Session
Matching-adjusted indirect comparison for belantamab mafodotin-blmf with pomalidomide and dexamethasone vs daratumumab with pomalidomide and dexamethasone in relapsed/refractory multiple myeloma	M. Beksac	Abstract #PF832 Poster Session
Gaps in access to chimeric antigen receptor T-cell therapy post leukapheresis: Waiting time and treatment patterns in relapsed/refractory multiple myeloma: real-world evidence from US claims	M. Purser	Abstract #PS1937 Poster Session
Extrapolated progression-free survival with belantamab mafodotin-blmf/lenalidomide/ dexamethasone exceeds 7 Years in intermediate-fit and frail, transplant-ineligible, newly diagnosed multiple myeloma	E. Terpos	Abstract #PF789 Poster Session

Momelotinib

Abstract Name	**Presenter**	**Presentation details**
Characterization of symptoms after immediate transition from ruxolitinib to momelotinib in patients with myelofibrosis: Post hoc analyses of the phase 3 SIMPLIFY-1 and SIMPLIFY-2 trials	P. Vachhani	Abstract #PS2001 Poster Session
Outcomes with momelotinib in patients with intermediate-1– vs intermediate-2–/high-risk myelofibrosis: Post hoc analyses of the phase 3 SIMPLIFY-1 and MOMENTUM trials	P. Bose	Abstract #PS1995 Poster Session
Real-world hematologic outcomes with momelotinib in patients with myelofibrosis and anemia: A German retrospective chart review	H. Al-Ali	Abstract #PB3455 Online Publication
ATLAS: A randomized, double-blind, placebo-controlled, adaptive seamless phase 2/3 study to assess the safety and efficacy of momelotinib in patients with VEXAS syndrome	D. Beck	Abstract #PB3163 Online Publication
Anemia recovery identifies prognostic heterogeneity in cytopenic myelofibrosis: A population based real-world analysis	R. Garcia Delgardo	Abstract #PB3448 Online Publication
Real-world characteristics, treatment patterns, and survival in patients with myelofibrosis and those using ruxolitinib: A nationwide study stratified by baseline and early transfusion status	Y. Chen	Abstract #PB3503 Online Publication

Full list of Alliance, investigator-initiated studies and supported collaborative studies at EHA:

Abstract Name	Presenter	Presentation details
MRD-guided maintenance therapy with belantamab mafodotin-blmf and lenalidomide after auto-HCT in newly diagnosed multiple myeloma: Interim analysis	Y. Aljawai	Abstract #PS1878 Poster Session
De-escalated dosing of belantamab mafodotin-blmf plus Vd reduces the incidence of ocular events while maintaining efficacy in relapsed/refractory multiple myeloma: A Czech multicenter phase 2 study	T. Popkova	Abstract # PS1870 Poster Session
High MRD negativity rates and prolonged PFS with belantamab mafodotin-blmf plus daratumumab, lenalidomide, and dexamethasone in transplant ineligible newly-diagnosed myeloma: Results of the BelaDRd study	E. Terpos	Abstract #S204 Oral Abstract Session
A phase I/II study of gilteritinib and momelotinib in adults with relapsed or refractory FLT3-mutated acute myeloid leukemia	L. Campoverde	Abstract #PF550 Poster Session
Dynamic cytopenia patterns in myelofibrosis: A real-world analysis from the ERNEST-3 registry	T. Barbui	Abstract #PS2002 Poster Session
Phase 2 study to assess the safety and efficacy of bomedemstat (IMG-7289) in combination with momelotinib in patients with myelofibrosis	C. Rinaldi	Abstract #PB3508 Online Publication

About GIST
Gastrointestinal stromal tumors (GIST) are the most common subtype of soft tissue sarcoma, with about 80,000 to 120,000 patients diagnosed with GIST per year worldwide.[1] GIST typically presents in the gastrointestinal tract with 80% of cases driven by mutations in the KIT gene that lead to the growth, proliferation and survival of tumor cells (primary or activating mutations in exons 9 and 11).[2] Additionally, about 90% of patients treated in the first-line develop new KIT mutations (secondary or resistance mutations in exons 13 and 17) that typically lead to relapse with limited therapeutic options.[3] There are no approved tyrosine kinase inhibitors (TKIs) that inhibit the full spectrum of clinically relevant primary and secondary mutations in KIT.

About multiple myeloma
Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[4,5] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[6] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[7] Many patients with multiple myeloma are treated in a community cancer setting, leaving an urgent need for new, effective therapies with manageable side effects that can be administered outside of an academic centre.[8,9]

About endometrial cancer
Endometrial cancer is found in the inner lining of the uterus, known as the endometrium. Endometrial cancer is the most common gynecologic cancer in developed countries,[10] with an estimated 1.6 million people living with active disease at any stage and 417,000 new cases reported each year worldwide. **Error! Bookmark not defined.** Incidence rates are expected to rise by approximately 40% between 2020 and 2040.[11] In the United States, ~68,000 people will be diagnosed with endometrial cancer in 2026. Endometrial cancer makes up more than 90% of uterine cancers.[12] Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.[13] Among patients with primary advanced or recurrent endometrial cancer, approximately 75% have mismatch repair proficient/microsatellite stable tumors (MMRp/MSS).[14]

About myelofibrosis
Myelofibrosis is a rare blood cancer that disrupts the body's normal production of blood cells because of dysregulated Janus kinase (JAK)-signal transducer and activator of transcription protein signalling. The clinical hallmarks of myelofibrosis are splenomegaly (enlarged spleen), severely low blood counts, including anemia and

thrombocytopenia, and debilitating constitutional symptoms, such as fatigue, night sweats and bone pain, attributable to ineffective hematopoiesis and excessive production of proinflammatory cytokines.[15,16]

About ovarian cancer
Ovarian cancer is the eighth most common cancer in women worldwide.[17] Despite high response rates to platinum-based chemotherapy in the first-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.[18]

About velzatinib (IDRX-42)
Velzatinib is a highly selective, investigational small molecule tyrosine kinase inhibitor (TKI) designed to target all key KIT mutations in GIST. The US Food and Drug Administration (FDA) has granted velzatinib Fast Track designation for the treatment of patients with GIST after disease progression on or intolerance to imatinib, and Orphan Drug designations for the treatment of GIST.

About belantamab mafodotin-blmf
Belantamab mafodotin-blmf is an antibody-drug conjugate comprising a humanized b-cell maturation antigen (BCMA) 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.

INDICATION AND IMPORTANT SAFETY INFORMATION for BLENREP (belantamab mafodotin-blmf)

INDICATION
BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

WARNINGS AND PRECAUTIONS
Ocular Toxicity
BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was

85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

BLENREP Risk Evaluation and Mitigation Strategy (REMS)
BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

Thrombocytopenia
Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

Embryo-fetal Toxicity
Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.

ADVERSE REACTIONS
The most common adverse reactions (≥20%) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.

The most common Grade 3 or 4 (≥10%) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

Please see full Prescribing Information, including BOXED WARNING, for BLENREP.

About dostarlimab-gxly
Dostarlimab-gxly, a programmed death receptor-1 (PD-1)-blocking antibody, is the backbone of GSK's ongoing immuno-oncology-based research and development program. A robust clinical trial program includes studies of dostarlimab-gxly alone and in combination with other therapies in gynecologic, colorectal and lung cancers, as well as where there are opportunities for transformational outcomes.

Dostarlimab-gxly 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 dostarlimab-gxly.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for JEMPERLI (dostarlimab-gxly)

INDICATIONS

- 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).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (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.

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% (30/241) 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 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 (≥20%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

The most common adverse reactions (≥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.

Please see full Prescribing Information, including Medication Guide.

About momelotinib
Momelotinib has a differentiated mechanism of action, with inhibitory ability along three key signalling pathways: JAK1, JAK2, and activin A receptor, type I (ACVR1).[19,20,21,22] Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly.[19,20,22] Additionally, inhibition of ACVR1 leads to a decrease in circulating hepcidin levels, potentially contributing to anemia-related benefit.[19,20,21,22]

INDICATION AND IMPORTANT SAFETY INFORMATION for OJJAARA (momelotinib)

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 × 10^9/L, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than 50 × 10^9/L.
- Severe neutropenia, absolute neutrophil count (ANC) less than 0.5 × 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.

Severe Cutaneous Adverse Reactions (SCARs)

- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist for evaluation and management.
- If etiology is considered to be associated with OJJAARA, permanently discontinue OJJAARA and do not reintroduce OJJAARA in patients who have experienced SCARs or other life-threatening cutaneous reactions during treatment with OJJAARA.

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.

Symptom Exacerbation Following Interruption or Discontinuation of Treatment

- Following discontinuation of JAK inhibitors, including OJJAARA, signs and symptoms from myeloproliferative neoplasms may flare. Some patients with MF have experienced one or more of the following after discontinuing JAK inhibitors: fever, respiratory distress, hypotension, disseminated intravascular coagulation, or multi-organ failure.
- If one or more of these signs and symptoms occur after discontinuation of OJJAARA, evaluate for and treat any intercurrent illness and consider restarting OJJAARA. Instruct patients not to interrupt or discontinue therapy without consulting their healthcare provider. When discontinuing or interrupting therapy for reasons other than potentially life-threatening toxicities, consider tapering the dose of OJJAARA gradually rather than discontinuing abruptly.

Adverse Reactions

- The most common adverse reactions (≥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.

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

- Momelotinib 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).

To report SUSPECTED ADVERSE REACTIONS, contact GSK at gsk.public.reportum.com or 1-888-825-5249, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Patient Information, for OJJAARA.

About niraparib

Niraparib is an oral, once-daily Poly (ADP-ribose) polymerase (PARP) inhibitor indicated in the US for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; and 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 and who have been selected based on a US FDA-approved companion diagnostic for niraparib.

INDICATION AND IMPORTANT SAFETY INFORMATION for ZEJULA (niraparib) (PRIMA-1LM of HRD-Positive aOC)

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 platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) – positive status defined by either a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability. Select patients for therapy based on an FDA-authorized 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, of patients within the HRD-positive population, MDS/AML occurred in 8 out of 245 (3.3%) patients treated with ZEJULA, and in 3 out of 125 (2.4%) patients treated with placebo with a follow-up of 6.1 years. The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 5.5 months to 5 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. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients in PRIMA. 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 cardiovascular effects 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. 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 Treatment of HRD-Positive Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of all patients who received ZEJULA in PRIMA were thrombocytopenia (66%), anemia (65%), nausea (62%), fatigue (52%), musculoskeletal pain (46%), neutropenia (43%), constipation (40%), leukopenia (29%), headache (27%), insomnia (25%), vomiting (23%), dyspnea (21%), decreased appetite (20%), dizziness (20%), cough (20%), hypertension (20%), AST/ALT elevation (14%), acute kidney injury (13%), and anxiety (12%).

Common lab abnormalities (Grades 1-4) in ≥25% of all patients who received ZEJULA in PRIMA included: decreased hemoglobin (85%), decreased leukocytes (72%), decreased platelets (71%), decreased neutrophils (64%), increased glucose (62%), decreased lymphocytes (55%), increased alkaline phosphatase (48%), increased creatinine (40%), decreased magnesium (39%), increased AST (35%), increased ALT (32%), and increased calcium (31%).

Please see the full Prescribing Information for ZEJULA.

To report SUSPECTED ADVERSE REACTIONS, contact GSK at gsk.public.reportum.com or 1-888-825-5249, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

PRT to determine if MedWatch/VAERs statement is needed (depending on modular format for certain digital assets, medwatch may already be included in direct proximity to ISI – would not need to duplicate)

GSK in oncology
Our ambition in oncology is to help increase overall quality of life, maximize survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid tumors. This includes accelerating priority programs such as antibody-drug conjugates targeting B7-H3 and B7-H4, and IDRX-42, a highly selective KIT tyrosine kinase inhibitor.

Press release
For media and investors only

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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Notes
*United States Adopted Names Council approval pending for the name velzatinib

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 "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q1 Results for 2026.

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