Press release

For media and investors only

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GSK data at ASH show potential to redefine outcomes for people living with blood cancers

- Long-term data from DREAMM-7 and DREAMM-8 highlight sustained benefits of belantamab mafodotin-blmf in treatment of relapsed or refractory multiple myeloma
- DREAMM-9 evaluates an optimal dosing schedule for belantamab mafodotin-blmf in newly diagnosed multiple myeloma
- Updated analyses from MOMENTUM, SIMPLIFY-1, and preliminary data from ODYSSEY reinforce momelotinib's potential in achieving spleen and anemia benefits associated with survival outcomes in myelofibrosis

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GSK plc (LSE/NYSE: GSK) will present new data from its hematology portfolio at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition (December 6 - 9), reinforcing its potential to redefine outcomes for patients with difficult-to-treat blood cancers.

New results from the DREAMM program for belantamab mafodotin-blmf further support its potential to extend remission in relapsed or refractory multiple myeloma, with development in newly diagnosed patients underway

Key presentations include:

- Updated results from DREAMM-8 (median 35.8 months of follow-up) explore depth of response and sustained benefit for patients with relapsed or refractory multiple myeloma (Abstract #2264)
- DREAMM-7 post hoc analysis explores patient characteristics and outcomes associated with duration and depth of response in responders with progression-free survival (PFS) greater than three years (Abstract #2262)
- Combined DREAMM-7 and DREAMM-8 subgroup analysis evaluates PFS and minimal residual disease negativity rates following treatment with belantamab mafodotin-blmf versus standard of care therapies in patients with functional high-risk relapsed or refractory multiple myeloma, a population with typically poor outcomes (Abstract #5820)
- Analyses from DREAMM-9 in transplant-ineligible newly diagnosed multiple myeloma patients assess the potential for higher initial dose intensity to optimize response, followed by dosing schedule extensions to minimize the potential for eye-related side effects (Abstract #5840)

New analyses for momelotinib build on positive MOMENTUM and SIMPLIFY trial results, assessing spleen and anemia endpoints alongside overall survival, and early results from a first combination trial will be presented

Additional analyses from MOMENTUM and SIMPLIFY-1 highlight the ability of momelotinib to improve hemoglobin levels and achieve a dual response — both transfusion independence and spleen volume reduction — and the association of these outcomes with survival outcomes in myelofibrosis patients with or without prior JAK inhibitor therapy. (Abstract #2023)

Preliminary efficacy and safety results will be shared from the ODYSSEY trial — the first combination trial for momelotinib evaluating it in combination with luspatercept. The trial explores whether momelotinib's unique dual mechanism, targeting both anemia and splenomegaly, can serve as a foundational backbone in future combination therapies to deliver deeper, more durable responses. (Abstract #3803)

Additional presentations include:

- Post hoc analysis from the MOMENTUM trial assesses the association between increased momelotinib exposure and greater anemia-related benefits in patients previously treated with JAK inhibitors (Abstract #5580)
- Analyses show momelotinib survival results in intermediate- and high-risk patients as defined by the RR6 model following switch from ruxolitinib, a standard of care, at or before 6 months (Abstract #5579)

Full list of GSK's presentations at ASH:

Belantamab mafodotin-blmf

Abstract name	Presenter	Presentation details
Deep responses and durable outcomes in patients treated with belantamab mafodotin-blmf plus pomalidomide and dexamethasone from long-term follow-up of the phase 3 DREAMM-8 study	S. Trudel	Poster, Abstract #2264
Long-term responders from the phase 3 DREAMM-7 study of belantamab mafodotin-blmf plus bortezomib and dexamethasone vs daratumumab plus bortezomib and dexamethasone in relapsed/refractory multiple myeloma	V. Hungria	Poster, Abstract #2262
Functional high-risk relapsed/refractory multiple myeloma (RRMM) outcomes with belantamab mafodotin-blmf (belamaf): DREAMM-7 and DREAMM-8 subgroup analysis	M. Mateos	Poster, Abstract #5820
Health-related quality of life with belantamab mafodotin-blmf in patients with relapsed or refractory multiple myeloma (RRMM): An exploratory analysis of overall quality of life in DREAMM-7	S. Lonial	Poster, Abstract #4029
Belantamab mafodotin-blmf (Belamaf) in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for patients (pts) with transplant-ineligible (TI) newly diagnosed multiple myeloma (NDMM): A focus on treatment efficacy and management/resolution of ocular events in the Phase 1 DREAMM-9 study	S. Usmani	Poster, Abstract #5840
Patients with relapsed/refractory multiple myeloma who achieved sustained minimal residual disease negativity in the DREAMM-7 trial	M. Mateos	Poster, Abstract #2265
Impact of belantamab mafodotin-blmf–containing regimens on renal	M. Lacerda	Poster, Abstract #2260

function in patients with relapsed/refractory multiple myeloma (RRMM) and mild/moderate renal impairment in the DREAMM-7 and DREAMM-8 trials		
Belantamab mafodotin-blmf (belamaf) ocular events are manageable and reversible with dose modifications guided by standard assessments	S. Lonial	Poster, Abstract #4055
An exploratory analysis of health-related quality of life measures with belantamab mafodotin-blmf in combination with pomalidomide and dexamethasone (BPd) in patients with relapsed or refractory multiple myeloma (RRMM) enrolled in DREAMM-8	P. Richardson	Poster, Abstract #2284
Patient-reported outcomes from DREAMM-7 and DREAMM-8 using the EQ-5D-3L, patient global impression of severity, and patient global impression of change	S. Trudel	Poster, Abstract #5823
Integrated modeling analyses for belantamab mafodotin-blmf in combination with standard of care in patients with relapsed/refractory multiple myeloma (RRMM) From DREAMM-6, DREAMM-7, and DREAMM-8	F. Carreño	Poster, Abstract #4043
Years of life lost to multiple myeloma remains high: A targeted literature review	A. Bates	Poster, Abstract #2804
Life-years and quality-adjusted life-years with belantamab mafodotin-blmf, bortezomib, and dexamethasone vs alternative regimens in patients with relapsed/refractory multiple myeloma who received ≥1 prior line of therapy	A. Suvannasankha	Poster, Abstract #4041
Chimeric antigen receptor T cells in real-world care of multiple myeloma: Patient characteristics and healthcare resource utilization	N. Boytsov	Poster, Abstract #2787
Bispecific antibodies in real-world care of multiple myeloma: Patient characteristics and healthcare resource utilization	N. Boytsov	Poster, Abstract #2790
Characteristics of patients with relapsed/refractory multiple myeloma (RRMM) in Europe and the US	L. Kalilani	ePublication

Indirect treatment comparison of belantamab mafodotin-blmf + pomalidomide + dexamethasone Versus comparator regimens in lenalidomide-exposed relapsed/refractory multiple myeloma: A network meta-analysis	J. Richter	ePublication
Administration- and adverse event-related costs among patients with multiple myeloma treated with B-cell maturation antigen (BCMA)-targeted agents	N. Boytsov	ePublication

Momelotinib

Abstract name	**Presenter**	**Presentation details**
Dual transfusion independence and spleen volume reduction is associated with overall survival in patients with myelofibrosis treated with momelotinib: Post hoc analyses of SIMPLIFY-1 and MOMENTUM	B. Psaila	Poster, Abstract #2023
Association between momelotinib exposure and hemoglobin improvement in patients with myelofibrosis and anemia: An exposure-response and time-to-event analysis	V. Gupta	Poster, Abstract #5580
Preliminary experience from the ODYSSEY trial: Efficacy and safety of momelotinib in combination with luspatercept in patients with transfusion-dependent myelofibrosis	P. Bose	Poster, Abstract #3803
Survival outcomes in ruxolitinib-treated patients with myelofibrosis following crossover to momelotinib: Application of the response to ruxolitinib at 6 months (RR6) prognostic model to SIMPLIFY-1	R. Rampal	Poster, Abstract #5579
Impact of hemoglobin improvement with momelotinib on survival in patients with myelofibrosis and anemia: Post hoc analyses of the SIMPLIFY-1 and MOMENTUM trials	P. Vachhani	Poster, Abstract #5581
Transfusion independence with momelotinib regardless of baseline erythropoietin levels in the Phase 3 SIMPLIFY-1 trial	S. Oh	Poster, Abstract #2025
Survival and clinical outcomes in patients with myelofibrosis and new or worsening anemia treated with ruxolitinib: A systematic review and meta-analysis	A. Kuykendall	Poster, Abstract #2031

Impact of new or worsening anemia and thrombocytopenia on clinical outcomes in JAK inhibitor–naive myelofibrosis patients treated with ruxolitinib	V. Gupta	Poster, Abstract #3809
Unveiling prognostic subtypes in myelofibrosis through routine blood counts: a population-based analysis of the cytopenic and proliferative phenotypes in andalusia, spain	R. Garcia Delgardo	ePublication
Discovery of drug combinations with momelotinib to improve myelofibrosis outcomes	S. O'Brien	ePublication
Momelotinib's unique polypharmacology supports indication expansion beyond myelofibrosis	S. O'Brien	ePublication

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

Abstract Name	Presenter	Presentation Details
Belantamab mafodotin-blmf		
Target antigen density impacts clinical response in multiple myeloma patients undergoing treatment with elotuzumab and belantamab mafodotin-blmf	N. Neparidze	ePublication
Can a patient questionnaire (VRAT) reduce the need for ocular examinations with less frequent belantamab mafodotin-blmf combined with bortezomib and dexamethasone? The UKMRA PROMMISE D trial	R. Popat	Poster, Abstract #4065
Belantamab mafodotin-blmf, nirogacestat, and pomalidomide in patients with relapsed/refractory multiple myeloma	M. Hultcrantz	Poster, Abstract #4060
Hematologist-led ocular safety management using the vra tool with belantamab mafodotin-blmf plus lenalidomide/dexamethasone in transplant ineligible NDMM: updated results from the RP2D cohort	E. Terpos	Poster, Abstract #4038
Phase II trial of belantamab mafodotin-blmf, carfilzomib, pomalidomide, and dexamethasone in multiple myeloma following BCMA CAR T-cell therapy	B. Derman	Poster, Abstract #5832
Momelotinib		
Preliminary data from the Phase I/II study of nuvisertib, an oral investigational selective PIM1	J. Mascarenhas	Oral, Abstract #482

inhibitor, in combination with momelotinib showed clinical responses in patients with relapsed/refractory myelofibrosis		

About multiple myeloma

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[1,2] There are approximately 180,000 new cases of multiple myeloma diagnosed globally each year.[3] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[4]Many patients with multiple myeloma, including approximately 70% in the US, 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 center.[5,6,7]

About myelofibrosis

Myelofibrosis is a rare blood cancer that disrupts the body's normal production of blood cells because of dysregulated 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.[8,9]

About belantamab mafodotin-blmf

Belantamab mafodotin-blmf is a monoclonal ADC (antibody-drug conjugate) comprising a humanized BCMA (B-cell maturation antigen) conjugated to the cytotoxic agent monomethyl 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.

In October 2025, the US FDA approved[10] belantamab mafodotin-blmf under the brand name *Blenrep* in combination with bortezomib and dexamethasone (BVd) 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.

Belantamab mafodotin in combination with bortezomib and dexamethasone and belantamab mafodotin in combination with pomalidomide and dexamethasone are approved in 2L+ relapsed or refractory multiple myeloma in the European Union[11], UK[12], Japan[13], Canada, Switzerland and Brazil.

Applications are currently under review in other markets globally, including China[14] where the application is based on the results of DREAMM-7 and has been granted Breakthrough Therapy Designation and Priority Review.

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

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 momelotinib
Momelotinib 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).[15,16,17,18] Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly.[15,16,17] Additionally, inhibition of ACVR1 leads to a decrease in circulating hepcidin levels, potentially contributing to anemia-related benefit.[15,16,17,18]

In September 2023, the US Food and Drug Administration approved[19] momelotinib under the brand name *Ojjaara* for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis or secondary myelofibrosis (post-polycythaemia vera and post-essential thrombocythemia), in adults with anemia.

In January 2024, the European Commission granted marketing authorization[20] for momelotinib for disease-related splenomegaly (enlarged spleen) or symptoms in adult patients with moderate to severe anemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythemia myelofibrosis and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib. Momelotinib was also approved[21] by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom to treat the symptoms experienced by adult myelofibrosis patients who have moderate or severe anemia.

In June 2024, the Japan Ministry of Health, Labor and Welfare (MHLW) approved[22] momelotinib for the treatment of myelofibrosis. Momelotinib is currently approved in 21 countries and applications are under review in other markets globally.

INDICATION AND IMPORTANT SAFETY INFORMATION for OJJAARA (momelotinib)

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.

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 for OJJAARA.

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.

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 www.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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q3 Results for 2025.

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