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## GSK data at ASCO and EHA showcase latest research and innovation across the oncology portfolio

- Latest data on belantamab mafodotin combinations underscore the potential to transform treatment of 2L+ multiple myeloma
- New analyses from MOMENTUM and SIMPLIFY-1 trials at EHA emphasize importance of early intervention with *Ojjaara* (mometotinib)
- New data across phase III studies at ASCO show the impact of *Jemperli* (dostarlimab-gxly) and *Zejula* (niraparib) in advanced gynecologic cancers

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GSK plc (LSE/NYSE: GSK) today announced that new data across the oncology pipeline and portfolio will be presented in more than 60 abstracts at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting (May 30 – June 3) in Chicago, IL and the 30<sup>th</sup> European Hematology Association (EHA) Congress (June 12 - 15) in Milan, Italy. These results highlight GSK's research and development programs which aim to improve outcomes for patients with blood cancers, gynecologic cancers and other solid tumors through innovative therapeutic approaches.

### Reinforcing the potential for *belantamab mafodotin* to redefine treatment of relapsed/refractory multiple myeloma

At ASCO and EHA, GSK will share updated data from the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) program. Key presentations include:

- Updated progression-free survival (PFS) analysis from the DREAMM-8 study (EHA abstract #PF728).
- DREAMM-8 data shows the association of measurable residual disease (MRD) negativity with efficacy endpoints (ASCO abstract #7515).
- First presentation of safety and efficacy data from DREAMM-20 evaluating the unconjugated monoclonal antibody, belantamab. This represents an important first step towards exploring next-generation BCMA solutions. (ASCO abstract #7550).
- A new analysis from DREAMM-7 and DREAMM-8 which contextualize manageability of eye-related side effects, including impact on reading and driving (EHA abstract #PS1761).

### Importance of starting treatment early with *Ojjaara*, which may impact survival in myelofibrosis patients

At EHA 2025, new analyses from the pivotal MOMENTUM and SIMPLIFY-1 trials reinforce momelotinib as a standard of care in myelofibrosis (MF). The data explore the benefits of initiating treatment for myelofibrosis earlier, which could lead to better outcomes for patients. Presentations include:

- New post-hoc analyses from the MOMENTUM & SIMPLIFY-1 trials show addressing anemia and achieving hemoglobin improvement of 10 g/dL or above may positively impact overall survival (EHA abstract #PF828).
- New SIMPLIFY-1 subgroup data show the impact of patients achieving both  $\geq 35\%$  spleen volume reduction (SVR35) and transfusion independence responses with momelotinib, which are prioritized in treatment guidelines to support optimal long-term outcomes in patients (EHA abstract #PS1829).

### Understanding the impact of our medicines on quality of life for patients with gynecologic cancers

Findings from GSK's gynecologic cancers portfolio focus on understanding the patient treatment experience to better inform GSK's research efforts and clinical care. These include:

# Press release

## For media and investors only



- Results of the phase III FIRST-ENGOT-OV44 trial provides insight on the role of adding dostarlimab-gxly to platinum-based chemotherapy followed by niraparib maintenance, with or without bevacizumab, in first-line advanced ovarian cancer (ASCO abstract #LBA5506).
- Patient reported outcomes from the phase III PRIMA trial (ENGOT-OV26/GOG-3012) help inform healthcare providers on the impact of disease progression on quality of life in patients with newly diagnosed advanced ovarian cancer (ASCO abstract #5551).
- New post-hoc analysis from Part 1 of the phase III RUBY trial (EN6-NSGO/GOG-3031) evaluates time to changes in quality of life with dostarlimab-gxly plus chemotherapy (carboplatin-paclitaxel) compared to chemotherapy alone in patients with primary advanced or recurrent endometrial cancer (ASCO abstract #5600).

### **Full list of GSK's presentations at ASCO:**

#### **Belantamab Mafodotin**

<b>Abstract Name</b>	<b>Presenter</b>	<b>Presentation details</b>
Minimal residual disease (MRD) negativity (neg) in patients (pts) with relapsed or refractory multiple myeloma (RRMM) treated with belantamab mafodotin plus pomalidomide and dexamethasone (BPd) vs pomalidomide, bortezomib, and dexamethasone (PVd): Analysis from the DREAMM-8 trial	S. Trudel	Rapid Oral Abstract Session, #7515
Belantamab treatment of multiple myeloma: Results from part 1 of the first-in-human phase 1/2 DREAMM-20 trial	S. Kaptanis	Poster Session, #7550
DREAMM-8 study of belantamab mafodotin plus pomalidomide and dexamethasone (BPd) vs pomalidomide plus bortezomib and dexamethasone (PVd) in relapsed/refractory multiple myeloma (RRMM): A subgroup analysis in patients with high-risk cytogenetic features	S. Trudel	Poster Session, #7533
Belantamab mafodotin + pomalidomide + dexamethasone (BPd) vs daratumumab + bortezomib + dexamethasone (DVd) in relapsed/refractory multiple myeloma: An indirect comparison using patient-level data	M. Purser	Poster Session, #7536
Baseline ocular conditions and risk of ocular events in patients (pts) with relapsed/refractory multiple myeloma (RRMM) from the DREAMM-7 and DREAMM-8 trials of belantamab mafodotin (belamaf)	E. Manasanch	Poster Session, #7544
DREAMM-7 study of belantamab mafodotin plus bortezomib and dexamethasone (BVd) vs daratumumab plus bortezomib and dexamethasone (DVd) in relapsed/refractory multiple myeloma (RRMM): A subgroup analysis in patients (pts) with high-risk cytogenetic (HRC) features	S. Roy-Ghanta	Poster Session, #7546
Efficacy and safety outcomes in patients (pts) with renal impairment in the phase 3 DREAMM-7 and DREAMM-8 trials	M. Pitombeira de Lacerda	Poster Session, #7548



Abstract Name	Presenter	Presentation details
Design of the phase 3 DREAMM-10 study: Belantamab mafodotin plus lenalidomide and dexamethasone (BRd) vs daratumumab plus lenalidomide and dexamethasone (DRd) in transplant-ineligible, newly diagnosed multiple myeloma (TI-NDMM)	S. Lonial	Poster Session, TPS7567

#### Dostarlimab-gxly

Abstract Name	Presenter	Presentation details
Time to quality of life (QoL) improvement or deterioration in patients (pts) with primary advanced or recurrent endometrial cancer (pA/R EC) treated with dostarlimab-gxly plus chemotherapy in the ENGOT-EN6-NSGO/GOG-3031/RUBY trial	Z. Novak	Poster Session, #5600
Molecular testing in primary advanced or recurrent endometrial cancer: a cost-effectiveness analysis	Y. Chen	Poster Session, #5598
Time to subsequent therapy in patients (pts) with primary advanced or recurrent endometrial cancer (pA/rEC) receiving dostarlimab-gxly plus carboplatin-paclitaxel (DOST+CP) compared with pts receiving placebo plus CP (PBO+CP) in the ENGOT-EN6-NSGO/GOG-3031/RUBY trial	C. Matthews	Poster Session, #5601
The role of platinum-free interval in advanced endometrial cancer treatment: A real-world study of 843 patients	J. Chan	Poster Session, #5609
AZUR-4, a phase 2, open label, randomized study of neoadjuvant dostarlimab-gxly plus capecitabine plus oxaliplatin (CAPEOX) versus CAPEOX alone in previously untreated T4N0 or stage III mismatch repair proficient/microsatellite stable resectable colon cancer	G. Rasschaert	Poster Session, TPS3649

#### Niraparib

Abstract Name	Presenter	Presentation details
FIRST/ENGOT-OV44: A phase 3 clinical trial of dostarlimab-gxly (dost) and niraparib (nira) in first-line (1L) advanced ovarian cancer (aOC)	A. Hardy-Bessard	Oral Abstract Session, LBA5506
Impact of disease progression on health-related quality of life (HRQOL): Updated results from the PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib first-line (1L) maintenance therapy in patients with newly diagnosed advanced ovarian cancer (aOC)	M. Shahin	Poster Session, #5551
A phase 1/2 dose escalation study of the oral DNA polymerase theta inhibitor (POLQi) GSK4524101 ± niraparib in adults with advanced or metastatic solid tumors	V. Samnotra	Poster Session, TPS3174
First public and private ovarian cancer register in Chile: Potential effect of national formulary inclusion and COVID-19 pandemic on survival outcomes	C. Ibanez	Online publication, #e17586
First report on the characterization of public and private patients with ovarian cancer in Chile	C. Ibanez	Online publication, #e17588



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

<b>Abstract Name</b>	<b>Presenter</b>	<b>Presentation details</b>
Belantamab mafodotin plus lenalidomide/dexamethasone in newly diagnosed intermediate-fit & frail multiple myeloma patients: Long-term efficacy and safety from the phase 1/2 BELARD clinical trial	E. Terpos	Rapid Oral Abstract Session, #7512
Randomized phase II study of neoadjuvant (neoadj) anti-PD-1 dostarlimab-gxly (D) vs. D + anti-TIM-3 cobolimab (C) in high-risk resectable melanoma (mel) (NEO-MEL-T): Primary analysis	M. Mooradian	Oral Abstract Session, LBA9504
Niraparib plus PD-1 inhibitor for patients previously treated with immune checkpoint inhibitor for solid tumors with homologous recombination repair gene mutation (IMAGENE): A phase II basket study	T. Kato	Poster Session, #2613
A phase 1 study of PARP inhibitor (niraparib) plus HSP90 inhibitor (pimitepib) in solid tumors: Dose-expansion results from the NiraPim (EPOC2102) study	Y. Kawamoto	Poster Session, #3079
Cobolimab and dostarlimab-gxly in the first-line treatment of unresectable hepatoma: A multi-center, single arm, phase 2 trial	J. Acoba	Poster Session, #4099
Re-VOLVE: Phase II clinical trial in women with ovarian cancer progressing post-PARP inhibitor with treatment adapted to real-time assessment of evolving genomic resistance	P. Soberanis Pina	Poster Session, #5561
Biomarker results from the KGOG3056/NIRVANA-R trial: Maintenance niraparib plus bevacizumab in patients with platinum-sensitive, recurrent ovarian cancer previously treated with a PARP inhibitor	H. Cho	Poster Session, #5556
Quality of life and lifestyle changes during and after therapy in women with endometrial cancer: A global study of 1,066 patients (NOGGO, ENGOT, GCIG, ENGAGE-IMPROVE/EXPRESSION XI)	L. Chinczewski	Poster Session, #5606
Personalized biomarker-based treatment strategy in patients with recurrent/metastatic squamous cell carcinoma of the head and neck: Results of the biomarker-driven cohorts of the EORTC-HNCG-1559 trial (UPSTREAM)	R. Galot	Poster Session, #6028
IND.241: A Canadian Cancer Trials Group liquid-biopsy informed platform trial to evaluate treatment in CDK4/6-inhibitor resistant ER+/HER2- metastatic breast	D. Cescon	Poster Session, TPS1121
A global phase 3, open-label, randomized 2-arm study comparing the clinical efficacy and safety of niraparib with temozolomide in adult participants with newly-diagnosed, MGMT unmethylated glioblastoma	N. Sanai	Poster Session, TPS2096
Safety and tolerability of dostarlimab-gxly in combination antiretroviral therapy refractory HIV-associated Kaposi Sarcoma: preliminary results from the StarKap phase Ib trial	C. Fulgenzi	Online publication, #e14588



Abstract Name	Presenter	Presentation details
A phase 1 study of abemaciclib and niraparib as neoadjuvant therapy in hormone receptor positive and HER2 negative breast cancer	H. Ohm	Online publication, #e12598
PROMIS scores of cancer survivors in the Comprehensive Outcomes for After Cancer Health (COACH) study: An interim analysis	M. Hammer	Online publication, #e23182

**Full list of GSK presentations at EHA:**

**Belantamab Mafodotin**

Abstract Name	Presenter	Presentation details
Efficacy and safety outcomes in patients (pts) with renal impairment in the Phase 3 DREAMM-7 and DREAMM-8 trials	M. Pitombeira de LaCerde	Poster Session #PF701
DREAMM-8: Minimal residual disease negativity in patients with relapsed/refractory multiple myeloma treated with belantamab mafodotin, pomalidomide, and dexamethasone vs standard-of-care regimen	M. Dimopoulos	Poster Session, #PF726
Updated results from phase 3 DREAMM-8 study of belantamab mafodotin plus pomalidomide and dexamethasone vs pomalidomide plus bortezomib and dexamethasone in relapsed/refractory multiple myeloma.	M. Dimopoulos	Poster Session, #PF728
DREAMM-7 study of belantamab mafodotin + bortezomib + dexamethasone vs daratumumab + bortezomib + dexamethasone in relapsed/refractory multiple myeloma: a high-risk cytogenetic subgroup analysis	M. Mateos	Poster Session, #PF739
DREAMM-8 study of belantamab mafodotin + pomalidomide + dexamethasone vs pomalidomide + bortezomib + dexamethasone in relapsed/refractory multiple myeloma: a high-risk cytogenetic subgroup analysis	M. Dimopoulos	Poster Session, #PF741
Baseline ocular conditions and incidence of ocular events in patients (pts) with relapsed/refractory multiple myeloma (RRMM) from the DREAMM-7 and DREAMM-8 trials of belantamab mafodotin (belamaf)	M. Dimopoulos	Poster Session, #PF759
European clinical views on the challenges of treating patients with autologous chimeric antigen receptor t-cell therapy and bispecific antibodies in multiple myeloma	M. Purser	Poster Session, # PF760
Belantamab for the treatment of multiple myeloma: results from part 1 of the first-in-human phase 1/2 DREAMM-20 trial.	H. Quach	Poster Session, #PF783
Belantamab mafodotin treatment triggers immunologic and inflammatory cell death in myeloma, with implications for the tumour microenvironment and duration of response	E. Watson	Poster Session: #PS1685



Abstract Name	Presenter	Presentation details
DREAMM-7 study of belantamab mafodotin + bortezomib + dexamethasone vs daratumumab + bortezomib + dexamethasone in relapsed/refractory multiple myeloma: efficacy in patients by subsequent therapy	V. Hungria	Poster Session, #PS1734
Real-world effectiveness and safety of belantamab mafodotin (belamaf) monotherapy in patients (pts) with relapsed/refractory multiple myeloma (RRMM) treated in Europe	M. Cavo	Poster Session, #PS1741
Characterization of ophthalmic examination findings (OEFs) and impact on reading and driving in patients with relapsed/refractory multiple myeloma (RRMM) treated with belantamab mafodotin (belamaf)	R. Hajek	Poster Session, #PS1761
Characterization of infections in patients with relapsed/refractory multiple myeloma (RRMM) treated with belantamab mafodotin (belamaf)-based regimens from DREAMM-7 and DREAMM-8 trials	P. Robak	Poster Session, #PS1762
Real-world ocular monitoring and safety of belantamab mafodotin (belamaf) monotherapy in patients (pts) with relapsed/refractory multiple myeloma (RRMM) treated in Europe and the US	F. Schjesvold	Poster Session, #PS1771
Phase 3 DREAMM-10 study design: belantamab mafodotin plus lenalidomide and dexamethasone vs daratumumab plus lenalidomide and dexamethasone in transplant-ineligible newly-diagnosed multiple myeloma	M. Dimopoulos	Poster Session: #PS1793
Belantamab mafodotin + pomalidomide + dexamethasone (BPd) vs daratumumab + bortezomib + dexamethasone (DVd) in relapsed/refractory multiple myeloma: an indirect comparison using patient-level data	M Beksac	Online publication, #PB2895
Belantamab mafodotin, bortezomib, and dexamethasone vs daratumumab, bortezomib, and dexamethasone in relapsed/refractory multiple myeloma: Analysis of the China subpopulation in the DREAMM-7 study	C. Fu	Online publication, #PB2935
Clinical outcomes of relapsed or refractory multiple myeloma overall and among lenalidomide-refractory patients in East Asia: A targeted literature review	Y. Tao	Online publication, #PB2969
Treatment Patterns and Outcomes in Multiple Myeloma: A Retrospective Analysis of Clinical and Demographic Characteristics in Argentina and Brazil (2018-2024)	V Hungria	Online publication, #PB2911
Treatment patterns at first relapse and their outcomes in multiple myeloma; a Finnish RWD study	J Lievonen	Online publication, #PB2936





## Momelotinib

Abstract Name	Presenter	Presentation details
Survival impact and kinetics of hemoglobin improvement with momelotinib in patients with myelofibrosis and moderate to severe anemia: post hoc analyses of SIMPLIFY-1 and MOMENTUM	F. Palandri	Poster Session, #PF828
Impact of dual spleen response and transfusion independence on survival in JAK inhibitor-naïve patients with myelofibrosis and anemia treated with momelotinib: a subgroup analysis of SIMPLIFY-1	F. Palandri	Poster Session, #PS1829
The economic burden of myelofibrosis treated with ruxolitinib in France	J. Kiladijian	Poster Session, #PS1844
Trial in progress: MIDAS – a phase 2, randomized, open-label study of momelotinib in patients with anemia due to lower-risk myelodysplastic syndromes	G. Garcia-Manero	Online publication, #PB2773
Clinical determinants of health-related quality of life in patients with Janus Kinase Inhibitor-experienced myelofibrosis	S. Conlon	Online publication, #PB3083

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

Abstract Name	Presenter	Presentation details
Interim analysis of MRD-guided maintenance therapy with belantamab mafodotin and lenalidomide after auto-HCT in newly diagnosed multiple myeloma	Y. Aljawai	Poster Session, #PF754
Real-world treatment patterns and clinical outcomes of relapsed/refractory multiple myeloma in Asia – an Asian myeloma network study	C. Soekojo	Poster Session: #PF760
Evaluation of a Novel Patient-Reported Tool Guiding Extended Dosing Schedule of Belantamab Mafodotin in Combination with Lenalidomide and Dexamethasone in Newly Diagnosed Multiple Myeloma Patients; Updated Ophthalmic Safety from a Phase 1/2 Trial of the Greek Myeloma Study Group	E. Terpos	Poster: #PS1769
Extended dosing schedule of Belantamab Mafodotin in combination with Daratumumab, Lenalidomide and Dexamethasone in Patients with Newly Diagnosed Multiple Myeloma: The Phase 1/2 BelaDRd Study	E. Terpos	Poster: #PF733
Real-World Clinical Practice in Italian Patients with Multiple Myeloma: Preliminary Analysis of the MY MYELOMA Multicenter Registry	G. Bertuglia	Poster: #PF775
A Multicenter Phase 2 Study Designed to Optimize the Schedule of Belantamab Mafodotin Plus Bortezomib and Dexamethasone in Relapsed Refractory Multiple Myeloma	T Popková	Poster: #PF734



### **About multiple myeloma**

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.<sup>1,2</sup> There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.<sup>3</sup> Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.<sup>4</sup> 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.<sup>5,6</sup>

### **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.<sup>7,8</sup>

### **About ovarian cancer**

Ovarian cancer is the eighth most common cancer in women worldwide.<sup>9</sup> 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.<sup>10</sup>

### **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,<sup>11</sup> with an estimated 1.6 million people living with active disease at any stage and 417,000 new cases reported each year worldwide.<sup>16</sup> Incidence rates are expected to rise by approximately 40% between 2020 and 2040.<sup>12</sup> In the United States, ~62,000 people will be diagnosed with endometrial cancer in 2025. Endometrial cancer makes up more than 90% of uterine cancers.<sup>13</sup> Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.<sup>14</sup> Among patients with primary advanced or recurrent endometrial cancer, approximately 75% have MMRp/MSS tumors.<sup>15</sup>

### **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 categorised as part of a group of cancers called colorectal cancer. Colorectal cancer is the third most commonly diagnosed cancer in the world.<sup>16</sup> In the US, it is estimated that approximately 46,220 individuals are diagnosed annually with rectal cancer.<sup>17</sup> Approximately 5-10% of all rectal cancers are dMMR/MSI-H, meaning that they contain abnormalities that affect the proper repair of DNA when copied in a cell.<sup>18</sup> Mismatch repair deficient status is a biomarker that has been shown to predict response to immune checkpoint blockade with PD-1 therapy.<sup>19,20</sup> Tumors with this biomarker are most commonly found in endometrial, colorectal and other gastrointestinal cancers but may also be found in other solid tumors.<sup>21,22,23,24</sup>

### **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.<sup>25</sup> 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.<sup>26</sup> Survival rates and mortality statistics for glioblastoma have been virtually unchanged for decades, highlighting the need to investigate new treatment options.<sup>26</sup>

### **About belantamab mafodotin**

Belantamab mafodotin is an investigational ADC comprising a humanized 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.

In April 2025, the UK Medicines and Healthcare products Regulatory Agency (MHRA) licensed belantamab mafodotin combinations for the treatment of relapsed or refractory multiple myeloma in adult patients who have received at least one prior therapy. In May 2025, the Japan Ministry of Health, Labour and Welfare approved belantamab mafodotin for the treatment of adults with relapsed or refractory multiple myeloma.





## **Indication and Important Safety Information for OJJAARA (mometotinib)**

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.



#### **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 ( $\geq 20\%$  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.

#### **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](https://gsk.public.reportum.com) or 1-888-825-5249 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](https://www.fda.gov/medwatch).

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

#### Indications and Important Safety Information for ZEJULA (niraparib) tablets 100 mg/200 mg/300 mg:

- 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
- 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 NOVA<sub>1</sub>, 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  $\geq 3$  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  $\geq 3$  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%), 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 g*BRCA*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 g*BRCA*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 accompanying Prescribing Information for ZEJULA tablets.**

#### **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).
- 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, 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% (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 ( $\geq 20\%$ ), 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 ( $\geq 20\%$ ) 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 full Prescribing Information for JEMPERLI.**

### GSK in oncology

Our ambition in oncology is to help increase overall quality of life and deliver practice-changing potential to modify 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 [us.gsk.com](https://us.gsk.com).

### GSK inquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Madison Goring	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)

# Press release

## For media and investors only



Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

### 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 Q1 Results for 2025.

### Registered in England & Wales:

No. 3888792

### Registered Office:

79 New Oxford Street  
London  
WC1A 1DG

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# Press release

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