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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 emphasise importance of early intervention with momelotinib
- New data across phase III studies at ASCO show the impact of dostarlimab and niraparib in advanced gynaecologic cancers

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 (30 May - 3 June) in Chicago, IL and the 30th European Hematology Association (EHA) Congress (12 - 15 June) in Milan, Italy. These results highlight GSK's research and development programmes which aim to improve outcomes for patients with blood cancers, gynaecologic cancers and other solid tumours 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) programme. 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 contextualise manageability of eye-related side effects, including impact on reading and driving (EHA abstract #PS1761).

Importance of starting treatment early with momelotinib 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 anaemia and achieving haemoglobin 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 ≥ 35% spleen volume reduction (SVR35) and transfusion independence responses with momelotinib, which are prioritised 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 gynaecologic cancers

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

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- Results of the phase III FIRST-ENGOT-OV44 trial provides insight on the role of adding dostarlimab to platinumbased 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 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

Abstract Name	Presenter	Presentation details
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 highrisk 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

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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	S. Lonial	Poster Session, TPS7567
myeloma (TI-NDMM)		

Dostarlimab

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 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 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 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 (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

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

Abstract Name	Presenter	Presentation details
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 (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 (pimitespib) in solid tumors: Dose-expansion results from the NiraPim (EPOC2102) study	Y. Kawamoto	Poster Session, #3079
Cobolimab and dostarlimab 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. Chinczweski	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 in combination antiretroviral therapy refractory HIV-associated Kaposi Sarcoma: preliminary results from the StarKap phase Ib trial	C. Fulgenzi	Online publication, #e14588

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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 LaCerda	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

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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

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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–naive 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 Mutiple 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 Optimized the Schedule of Belantamab Mafodotin Plus Bortezomib and Dexamethasone in Relapsed Refractory Multiple Myeloma	T Popková	Poster: #PF734

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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 more than 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 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. ^{5,6}

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 anaemia and thrombocytopenia, and debilitating constitutional symptoms, such as fatigue, night sweats and bone pain, attributable to ineffective haematopoiesis and excessive production of proinflammatory cytokines.^{7,8}

About ovarian cancer

Ovarian cancer is the eighth most common cancer in women worldwide. Despite high response rates to platinumbased 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.

About endometrial cancer

Endometrial cancer is found in the inner lining of the uterus, known as the endometrium. Endometrial cancer is the most common gynaecologic cancer in developed countries, ¹¹ with an estimated 1.6 million people living with active disease at any stage and 417,000 new cases reported each year worldwide. ¹⁶ Incidence rates are expected to rise by approximately 40% between 2020 and 2040. ¹² In Europe, approximately 121,000 people are estimated to be diagnosed with primary advanced or recurrent endometrial cancer each year. ¹³ Approximately 15-20% of patients with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis. ¹⁴ Among patients with primary advanced or recurrent endometrial cancer, approximately 75% have MMRp/MSS tumours. ¹⁵

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. ¹⁶ In the US, it is estimated that approximately 46,220 individuals are diagnosed annually with rectal cancer. ¹⁷ 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. ¹⁸ Mismatch repair deficient status is a biomarker that has been shown to predict response to immune checkpoint blockade with PD-1 therapy. ^{19,20}Tumours with this biomarker are most commonly found in endometrial, colorectal and other gastrointestinal cancers but may also be found in other solid tumours. ^{21,22,23,24}

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.²⁵ It accounts for more than half of all primary malignant brain tumours and is one of the most complex and treatment-resistant cancers, resulting in poor patient outcomes.²⁶ Survival rates and mortality statistics for glioblastoma have been virtually unchanged for decades, highlighting the need to investigate new treatment options.²⁶

About Blenrep (belantamab mafodotin)

Belantamab mafodotin is an ADC comprising a humanised 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.

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Important information for belantamab mafodotin in the United Kingdom

Indication

In the UK, belantamab mafodotin is indicated in adults for the treatment of multiple myeloma:

- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and
- in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide.

IMPORTANT SAFETY INFORMATION FOR BLENREP

More information can be found in the *Blenrep* Summary of Product Characteristics and Patient Information leaflets available on the MHRA Products website.

About Omjjara (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).^{27,28,29,30} Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly.^{27,28,30} Additionally, inhibition of ACVR1 leads to a decrease in circulating hepcidin levels, potentially contributing to anaemia-related benefit.^{27,28,29,30}

In September 2023, the US Food and Drug Administration <u>licensed</u>³¹ 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 anaemia.

In January 2024, the European Commission granted marketing authorisation ³² for momelotinib for disease-related splenomegaly (enlarged spleen) or symptoms in adult patients with moderate to severe anaemia 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 ³³ 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 anaemia.

In June 2024, the Japan Ministry of Health, Labour and Welfare (MHLW) <u>approved</u>³⁴ momelotinib for the treatment of myelofibrosis.

Important information for momelotinib in the EU

Indication

Momelotinib is indicated for the treatment of disease-related splenomegaly (enlarged spleen) or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

Refer to the <u>Omjjara EMA Reference Information</u> for a full list of adverse events and the complete important safety information in the EU.

About Zejula (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.

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Important information for niraparib in the EU

Indication

Niraparib is indicated:

- as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
- as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Refer to the <u>Zejula EMA Reference Information</u> for a full list of adverse events and the complete important safety information in the EU.

About Jemperli (dostarlimab)

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

In the US, dostarlimab is indicated in combination with carboplatin and paclitaxel, followed by dostarlimab as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer. This includes patients with MMRp/MSS and dMMR/MSI-H tumours. Dostarlimab is also approved as a single agent for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by a US FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation. Additionally, dostarlimab is indicated in the US for patients with dMMR recurrent or advanced solid tumours, as determined by a US FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The latter indication is approved in the US under accelerated approval based on tumour response rate and durability of response. Continued approval for this indication in solid tumours may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Dostarlimab 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, commercialisation, and manufacturing of dostarlimab and cobolimab (GSK4069889), a TIM-3 antagonist.

Important information for dostarlimab in the EU

Indication

Dostarlimab is indicated:

- in combination with carboplatin and paclitaxel, for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy;
- as monotherapy for treating adult patients with mismatch repair deficient (dMMR)/microsatellite instabilityhigh (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

Refer to the <u>Jemperli EMA Reference Information</u> for a full list of adverse events and the complete important safety information in the EU.

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

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gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes 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 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 Q1 Results for 2025.

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