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

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

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

DREAMM programme updates

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

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

Collaborations to improve patient care

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

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

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Full list of GSK's presentations at ASCO:

Belantamab Mafodotin

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

Dostarlimab

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

Niraparib

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

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

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

Cobolimab

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

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

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

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

About multiple myeloma

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

About dMMR/MSI-H rectal cancer

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

About glioblastoma

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

About belantamab mafodotin

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

Important information for *Blenrep* in Great Britain (GB)

Indication

***Blenrep* is indicated (GB):**

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- as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD39 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

Refer to the *Blenrep* UK [Summary of Product Characteristics](#)¹⁸ for a full list of adverse events and the complete important safety information in the United Kingdom.

About *Jemperli* (dostarlimab)

Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2.¹⁹

In the US, *Jemperli* is indicated in combination with carboplatin and paclitaxel, followed by *Jemperli* as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is dMMR, as determined by a US FDA-approved test, or MSI-H, and 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. The supplemental Biologics License Application supporting the newly approved indication in combination with carboplatin and paclitaxel for dMMR/MSI-H primary advanced or recurrent endometrial cancer received Breakthrough Therapy designation and Priority Review from the US FDA.

Jemperli is also 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).

Jemperli was discovered by AnaptysBio, Inc. and licensed to TESARO, Inc., under a collaboration and exclusive license agreement signed in March 2014. Under this agreement, GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of *Jemperli*, and cobolimab (GSK4069889), a TIM-3 antagonist.

Important Information for *Jemperli* in the EU

Indication

Jemperli is indicated:

- in combination with carboplatin-paclitaxel, for the treatment of adult patients with dMMR/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/MSI-H recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

Refer to the [Jemperli EMA Reference Information](#) for a full list of adverse events and the complete important safety information in the EU.

About *Zejula* (niraparib)

Zejula 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 *Zejula*.

Important Information for *Zejula* in the EU

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Indication

Zejula 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 [Zejula EMA Reference Information](#) for a full list of adverse events and the complete important safety information in the EU.

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).^{20,21, 22, 23} Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly.^{21, 23, 25} Additionally, inhibition of ACVR1 leads to a decrease in circulating hepcidin levels, potentially contributing to anaemia-related benefit.^{21,22,23, 24}

In September 2023, the [US Food and Drug Administration](#) licensed 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 thrombocythaemia), in adults with anaemia.

In January 2024, the [European Commission](#) granted marketing authorisation for *Omjjara* 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 thrombocythaemia myelofibrosis and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib. *Omjjara* was also approved 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.

Important Information for *Omjjara* in the EU

Indication

***Omjjara* 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 [Omjjara EMA Reference Information](#) for a full list of adverse events and the complete important safety information in the EU.

GSK in oncology

Oncology is an emerging therapeutic area for GSK where we are committed to maximising patient survival with a current focus on haematologic malignancies, gynaecologic cancers, and other solid tumours through breakthroughs in immuno-oncology and tumour-cell targeting therapies.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com](https://www.gsk.com).

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q1 Results for 2024.

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