Stock-exchange announcement

For media and investors only

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Blenrep (belantamab mafodotin) combinations in multiple myeloma application accepted for review by the European Medicines Agency

- Regulatory submission supported by phase III head-to-head DREAMM-7 and DREAMM-8 trials
- Trials showed significant progression-free survival benefit and positive overall survival trends for *Blenrep* combinations versus standard of care
- If approved, *Blenrep* plus BorDex or PomDex could redefine the relapsed/refractory multiple myeloma treatment landscape

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GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) has accepted the marketing authorisation application (MAA) for *Blenrep* (belantamab mafodotin) in combination with bortezomib plus dexamethasone (BorDex) or pomalidomide plus dexamethasone (PomDex) as a treatment for relapsed or refractory multiple myeloma. The EMA's Committee for Medicinal Products for Human Use (CHMP) will begin the formal review process to make a recommendation to the European Commission regarding this potential authorisation.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Today's milestone reinforces the potential for *Blenrep* to redefine outcomes for patients with multiple myeloma at or after first relapse. We are working to bring *Blenrep* to patients as quickly as possible given the high unmet need and the clinically robust effects of the *Blenrep* combinations in the DREAMM-7 and DREAMM-8 phase III head-to-head trials."

The application is based on interim results from the DREAMM-7 and DREAMM-8 phase III trials, which both met their primary endpoints, showing statistically significant and clinically meaningful improvements in progression-free survival (PFS) for the belantamab mafodotin combinations compared to standard of care combinations in relapsed or refractory multiple myeloma. The DREAMM-7 trial is evaluating belantamab mafodotin combined with BorDex versus daratumumab plus BorDex, while the DREAMM-8 trial is evaluating belantamab mafodotin in combination with PomDex versus bortezomib plus PomDex.

A positive overall survival (OS) trend was observed in both trials but was not statistically significant at the time of interim analysis. Follow-up for OS continues. Results also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses compared to the respective standard of care combinations. The safety and tolerability profiles of the belantamab mafodotin combinations in DREAMM-7 and DREAMM-8 trials were broadly consistent with the known profiles of the individual agents.

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, including approximately 50,000 new cases in Europe.[3,4] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[5]

About DREAMM-7

The DREAMM-7 phase III clinical trial is a multicentre, open-label, randomised trial evaluating the efficacy and safety of belantamab mafodotin in combination with BorDex compared to a combination of daratumumab and BorDex in patients with relapsed/refractory multiple myeloma who previously were treated with at least one prior line of multiple myeloma therapy, with documented disease progression during or after their most recent therapy.

A total of 494 participants were randomised at a 1:1 ratio to receive either belantamab mafodotin in combination with BorDex or a combination of daratumumab and BorDex. Belantamab mafodotin was scheduled to be dosed at 2.5mg/kg intravenously every three weeks.

The primary endpoint is PFS as per an independent review committee. The key secondary endpoints include OS, duration of response (DOR), and minimal residual disease (MRD) negativity rate as assessed by next-generation sequencing. Other secondary endpoints include overall response rate (ORR), safety and patient reported and quality of life outcomes.

Results from DREAMM-7 were first presented[6] at the American Society of Clinical Oncology (ASCO) Plenary Series in February 2024, shared in an encore presentation at the 2024 ASCO Annual Meeting, and published in the *New England Journal of Medicine*.

About DREAMM-8
The DREAMM-8 phase III clinical trial is a multicentre, open-label, randomised trial evaluating the efficacy and safety of belantamab mafodotin in combination with PomDex compared to a combination of bortezomib and PomDex in patients with relapsed/refractory multiple myeloma previously treated with at least one prior line of multiple myeloma therapy, including a lenalidomide-containing regimen, and who have documented disease progression during or after their most recent therapy. Compared to the patient population studied in the DREAMM-7 trial, patients in DREAMM-8 were more heavily pre-treated in that all had prior exposure to lenalidomide, 75% were refractory to lenalidomide, 25% had prior daratumumab exposure and of those most were daratumumab refractory.

A total of 302 participants were randomised at a 1:1 ratio to receive either belantamab mafodotin plus PomDex, or bortezomib plus PomDex.

The primary endpoint is PFS as per an independent review committee. The key secondary endpoints include OS and MRD negativity rate as assessed by next-generation sequencing. Other secondary endpoints include ORR, DOR, safety and patient reported and quality of life outcomes.

Results from DREAMM-8 were first presented[7] at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.

About *Blenrep*
Blenrep 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.

Refer to the *Blenrep* UK Summary of Product Characteristics[8] for a full list of adverse events and the complete important safety information in the United Kingdom.

GSK in oncology
GSK is committed to maximising patient survival through transformational medicines, with a current focus on breakthroughs in immuno-oncology and tumour-cell targeting therapies, and development in haematologic malignancies, gynaecologic cancers, and other solid tumours.

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.

GSK enquiries

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)
Investor Relations:	Nick Stone	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Josh Williams	+44 (0) 7385 415719	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(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 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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No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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[6] GSK press release issued 05 February 2024. DREAMM-7 phase III trial shows Blenrep combination nearly tripled median progression-free survival versus standard of care combination in patients with relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/dreamm-7-phase-iii-trial-shows-pfs-improvement-and-strong-os-trend-for-blenrep-combo-versus-soc-combo-in-multiple-myeloma/
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