

Stock-exchange announcement

For media and investors only



Issued: 23 October 2025, London UK

***Blenrep* approved by US FDA for use in treatment of relapsed/refractory multiple myeloma**

- Significant unmet need for patients requires new and novel treatments¹
- DREAMM-7 showed a 51% reduction in the risk of death and tripled median progression-free survival in 3L+ indicated population versus a daratumumab-based triplet²
- *Blenrep* is the only anti-BCMA accessible in the community setting where 70% of patients receive care, and with a new streamlined REMS programme³
- Robust clinical development is ongoing to advance *Blenrep* in earlier lines of treatment, including newly diagnosed patients⁴

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has approved *Blenrep* (belantamab mafodotin-blmf) in combination with bortezomib and dexamethasone (BVd) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory (IMiD) agent.

The *Blenrep* approval is supported by data from the pivotal DREAMM-7 phase III trial. In patients who had two or more prior lines of therapy (3L+), including a PI and an IMiD, *Blenrep* in combination demonstrated a clinically meaningful 51% reduction in the risk of death [HR 0.49, 95% confidence interval (CI): 0.32-0.76] and a tripled median progression-free survival (PFS) of 31.3 months [95% CI: 23.5-NR] versus 10.4 months [95% CI: 7.0-13.4] for a daratumumab-based triplet (DVd) [HR 0.31, 95% CI: 0.21-0.47]. The safety and tolerability profiles of the *Blenrep* combination were broadly consistent with the known profiles of the individual agents.²

Tony Wood, Chief Scientific Officer, GSK, said: “Today’s FDA approval of *Blenrep* is another significant milestone, providing potential for superior efficacy, including overall survival, to US patients. There is an urgent need for new and novel therapies, as nearly all patients with multiple myeloma experience relapse and re-treating with the same mechanism of action often leads to suboptimal outcomes. As the only anti-BCMA agent that can be administered across healthcare settings, including in community centres where 70% of patients receive care, *Blenrep* fulfils a major patient need. We believe *Blenrep* can redefine treatment for patients with multiple myeloma in all parts of the world, and we are accelerating its development in earlier lines of therapy to support its use across all stages of this difficult-to-treat cancer.”

Working closely with the FDA, *Blenrep* is available through a new, streamlined Risk Evaluation and Mitigation Strategy (REMS). The new REMS supports appropriate use and patient safety while reducing administrative burden through simplified patient forms, removal of duplicative checklists and efficient communication between HCPs and either optometrists or ophthalmologists monitoring eye care. GSK will also offer Together with GSK, an optional patient support programme available to all US patients prescribed *Blenrep*.

Data from the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical trial programme will be submitted to the National Comprehensive Cancer Network (NCCN) guidelines this year. Recent results from the DREAMM studies, alongside emerging real-world evidence, provide a growing body of data for *Blenrep*.^{5,6}

Sagar Lonial, MD, Chief Medical Officer, Winship Cancer Institute of Emory University in Atlanta, Georgia, Chair of Emory Department of Hematology and Medical Oncology, said: “With the approval of *Blenrep*, we now have a community-accessible BCMA-targeting agent with the potential to improve outcomes for patients following two or more prior lines of treatment, where options are limited. This approval marks an important advance in the US relapsed/refractory treatment landscape.”

Stock-exchange announcement

For media and investors only



Michael Andreini, President and Chief Executive Officer of the Multiple Myeloma Research Foundation and the Multiple Myeloma Research Consortium, said: “The reality for most patients with multiple myeloma is a relentless cycle of remission and relapse, as their disease becomes refractory to treatments. Patients urgently need more effective treatment options that can offer more quality time with their loved ones. We see the potential for *Blenrep* in combination to help patients achieve this.”

GSK is advancing the DREAMM clinical programme to demonstrate *Blenrep*'s potential benefit in earlier lines of treatment. Follow-up continues for overall survival (OS) in both DREAMM-7 and DREAMM-8 with data expected in early 2028, including in patients who have received only one prior line of therapy. DREAMM-10, a phase III trial in newly diagnosed transplant-ineligible patients, which represent over 70% of patients starting therapy, was initiated in Q4-2024.⁴ Interim efficacy and safety data for *Blenrep* as a first line treatment are expected in early 2028 with enrolment expanded to US sites to increase US patient representation in the study population. GSK continues to work with the FDA for US patients.

Approvals outside of the US

Blenrep combinations are approved in 2L+ relapsed or refractory multiple myeloma in the [European Union](#)⁷, [UK](#)⁸, [Japan](#)⁹, Canada, Switzerland and Brazil. Applications are currently under review in other markets globally, including [China](#)¹⁰ where the application is based on the results of DREAMM-7 and has been granted Breakthrough Therapy Designation and Priority Review.

About multiple myeloma

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.^{11,12} There are approximately 180,000 new cases of multiple myeloma diagnosed globally each year.¹³ Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.¹⁴ Many patients with multiple myeloma, including approximately 70% in the US, are treated in a community cancer setting, leaving an urgent need for new, effective therapies with manageable side effects that can be administered outside of an academic centre.^{3,15,16}

About *Blenrep*

Blenrep is a monoclonal ADC (antibody-drug conjugate) comprising a humanised BCMA (B-cell maturation antigen) 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.

Indication

In the US, *Blenrep* is indicated in combination with bortezomib and dexamethasone (BVD) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

Please see accompanying US Prescribing Information which will soon be available [here](#)¹⁷.

About DREAMM-7

DREAMM-7 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin combined with bortezomib plus dexamethasone (BVD) compared to daratumumab combined with bortezomib plus dexamethasone (DvD) in patients with relapsed or 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. The trial enrolled 494 participants who were randomised 1:1 to receive either BVD or DvD. Belantamab mafodotin was administered at a dose of 2.5mg/kg intravenously every three weeks in combination for the first eight cycles and then continued as a single agent. The primary endpoint was PFS as per an independent review committee, with secondary endpoints including 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.

[PFS results](#)¹⁸ were presented at the American Society of Clinical Oncology (ASCO) Plenary Series in February 2024 and published in the *New England Journal of Medicine*. [OS results](#)¹⁹ were presented at the American Society of Hematology (ASH) Annual Meeting in December 2024.

Stock-exchange announcement

For media and investors only



About DREAMM-10

DREAMM-10 is a multicentre, open-label, randomised phase III clinical trial in newly diagnosed transplant ineligible patients with multiple myeloma, evaluating belantamab mafodotin plus lenalidomide and dexamethasone (BRd) versus daratumumab plus lenalidomide and dexamethasone (DRd).⁴

GSK in oncology

Our ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid 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.

GSK enquiries

Media:	Simon Steel	+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:	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)
	Sam Piper	+44 (0) 7824 525779	(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 Q2 Results for 2025.

Registered in England & Wales:

No. 3888792

Registered Office:

79 New Oxford Street
London
WC1A 1DG

¹ Bruno A, et al. Recent real-world treatment patterns and outcomes in US patients with relapsed/refractory multiple myeloma. Expert Review of Hematology. 2020; Volume 13, Issue 9:1017–1025 <https://www.tandfonline.com/doi/full/10.1080/17474086.2020.1800451>.

² *Blenrep* US Prescribing Information.

³ Komodo claims data. Accessed 25 September 2025.

⁴ ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT06679101, A Study of Belantamab Mafodotin Administered in Combination With Lenalidomide and Dexamethasone (BRd) Versus Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Participants With Newly Diagnosed Multiple Myeloma (NDMM) Who Are Ineligible for Autologous Stem Cell Transplantation (TI-NDMM) (DREAMM-10). Available at: <https://clinicaltrials.gov/study/NCT06679101>.

Stock-exchange announcement

For media and investors only



⁵ Hungria V, Robak P, Hus M, et al. Belantamab Mafodotin, Bortezomib, and Dexamethasone for Multiple Myeloma. *N Engl J Med*. 2024 Aug 1;391(5):393-407. doi: 10.1056/NEJMoa2405090. Epub 2024 Jun 1. PMID: 38828933.

⁶ Hungria V, Robak P, H Marek, et al. Belantamab Mafodotin, Bortezomib, and Dexamethasone Vs Daratumumab, Bortezomib, and Dexamethasone in Relapsed/Refractory Multiple Myeloma: Overall Survival Analysis and Updated Efficacy Outcomes of the Phase 3 Dreamm-7 Trial. Presented at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition. December 2024.

⁷ GSK press release issued 24 July 2025. Blenrep (belantamab mafodotin) combinations approved in EU for treatment of relapsed/refractory multiple myeloma. Available at: <https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combinations-approved-in-eu-for-treatment-of-relapsedrefractory-multiple-myeloma/>.

⁸ GSK press release issued 17 April 2025. Blenrep (belantamab mafodotin) combinations approved by UK MHRA in relapsed/refractory multiple myeloma. Available at: <https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combinations-approved-by-uk-mhra-in-relapsedrefractory-multiple-myeloma/>.

⁹ GSK press release issued 19 May 2025. Blenrep (belantamab mafodotin) combinations approved in Japan for treatment of relapsed/refractory multiple myeloma. Available at: <https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combinations-approved-in-japan/>.

¹⁰ GSK press release issued 9 December 2024. Blenrep (belantamab mafodotin) combination accepted for priority review in China in relapsed/refractory multiple myeloma. Available at: <https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combination-accepted-for-priority-review-in-china-in-relapsedrefractory-multiple-myeloma/>.

¹¹ Sung H, Ferlay J, Siegel R, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*. 2021;71(3):209-249. doi:10.3322/caac.21660.

¹² Kazandjian D. Multiple myeloma epidemiology and survival: A unique malignancy. *Semin Oncol*. 2016;43(6):676–681.doi: 10.1053/j.seminoncol.2016.11.004.

¹³ Global Cancer Observatory. International Agency for Research on Cancer. World Health Organization. Multiple Myeloma fact sheet. Available at: <https://gco.iarc.who.int/media/globocan/factsheets/cancers/35-multiple-myeloma-fact-sheet.pdf>. Accessed 5 March 2025.

¹⁴ Nooka AK, Kastiris E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. *Blood*. 2015;125(20). doi:10.1182/blood-2014-11-568923.

¹⁵ Gajra A, Zeleni A, Sannareddy A, et al. Barriers to Chimeric Antigen Receptor T-Cell (CAR-T) Therapies in Clinical Practice. *Pharmaceut Med*. 2022 Jun;36(3):163-171.

¹⁶ Crombie J, Graff T, Falchi L, et al. Consensus recommendations on the management of toxicity associated with CD3×CD20 bispecific antibody therapy. *Blood* (2024) 143 (16): 1565–1575.

¹⁷ US Prescribing Information. To be available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Blenrep/pdf/BLENREP-PI-MG.PDF.

¹⁸ 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/>.

¹⁹ GSK press release issued 09 December 2024. Blenrep shows significant overall survival benefit, reducing the risk of death by 42% in multiple myeloma at or after first relapse. Available at: <https://www.gsk.com/en-gb/media/press-releases/blenrep-shows-significant-overall-survival-benefit-reducing-the-risk-of-death-by-42-in-multiple-myeloma-at-or-after-first-relapse/>.