Stock-exchange announcement
For media and investors only

Issued: 19 May 2025, London UK

Blenrep (belantamab mafodotin) combinations approved in Japan for treatment of relapsed/refractory multiple myeloma

- Superior efficacy shown in two head-to-head phase III trials, including overall survival in DREAMM-7
- *Blenrep* combinations could redefine treatment as early as first relapse where more effective options are needed[1,2,3]
- Second major approval for *Blenrep* combinations, with more expected in 2025

GSK plc (LSE/NYSE: GSK) today announced the approval of *Blenrep* combinations by Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of adults with relapsed or refractory multiple myeloma. The approval is based on positive results from the DREAMM-7 and DREAMM-8 phase III trials evaluating *Blenrep* in combination with bortezomib plus dexamethasone (BVd) and in combination with pomalidomide plus dexamethasone (BPd), respectively, in patients with multiple myeloma who have received at least one prior therapy. The approval follows an orphan drug designation for *Blenrep* in Japan, which was granted based on its ability to address high unmet need for patients with multiple myeloma.

Superior efficacy results from the pivotal DREAMM-7 and DREAMM-8 phase III trials in relapsed or refractory multiple myeloma support MHLW approval of *Blenrep* combinations. These include statistically significant and clinically meaningful progression-free survival (PFS) results for *Blenrep* combinations versus standards of care in both trials and overall survival (OS) in DREAMM-7.[2,3,4] The safety and tolerability profiles of the *Blenrep* combinations were broadly consistent with the known profiles of the individual agents.[2,3]

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Today's approval brings the benefits of *Blenrep* combinations to patients with relapsed or refractory multiple myeloma in Japan. Patients need additional treatment options at or after first relapse that can extend remission and survival versus standard of care. *Blenrep* combinations have the potential to redefine treatment outcomes based on superior efficacy shown in two phase III trials, with the added advantage of in-office administration in both academic and community treatment settings."

Most patients with multiple myeloma experience relapse, and in Japan only about 43% remain alive five years after diagnosis.[5] *Blenrep* is the only anti-BCMA (B-cell maturation antigen) antibody-drug conjugate (ADC) approved in multiple myeloma, providing patients at or after relapse with a differentiated mechanism of action. *Blenrep* combinations can be administered to a range of patient types in any oncology treatment setting without complex pre-administration regimens or hospitalisation.

In the DREAMM-7 and DREAMM-8 clinical trials, *Blenrep* combinations consistently benefited a broad range of patients, including those with poor prognostic features or outcomes, such as high-risk cytogenetics or those refractory to lenalidomide. Both trials also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses versus the respective comparators.[2,3]

Eye-related side effects associated with *Blenrep* were successfully managed by extending time between infusions and through dose reductions, allowing patients to maintain benefit and resulting in low rates of discontinuation (≤9%) in both trials.[2,3] Eye exam findings and changes in visual clarity (known as visual acuity) resolved in 83% of occurrences; with the trials ongoing, the remaining occurrences were in patients with follow-up ongoing or lost to follow-up. There have been no confirmed cases of permanent bilateral vision loss (i.e., no permanent bilateral eye exam findings of 20/200 or worse) based on current *Blenrep* clinical trial data and previous monotherapy post-

marketing use.[6] The most commonly reported non-ocular adverse events (>30% of participants) in the *Blenrep* combination arm were thrombocytopenia (87%) and diarrhoea (32%) in DREAMM-7, and neutropenia (63%), thrombocytopenia (55%) and COVID-19 (37%) in the *Blenrep* combination arm of DREAMM-8.

This is the second major regulatory approval for *Blenrep* combinations for the treatment of relapsed or refractory multiple myeloma, following the first authorisation in the world last month by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Blenrep combinations are currently under review in all major markets globally, including in the US with a Prescription Drug User Fee Act (PDUFA) date of 23 July 2025,[7] European Union,[8] China (based on the results of DREAMM-7, with Breakthrough Therapy Designation for the combination and priority review for the application),[9] Canada, and Switzerland (with priority review for DREAMM-8).

About multiple myeloma
Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[10,11] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year, including more than 7,200 in Japan.[12,13,14,15] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[1] 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.[16,17]

About *Blenrep*
Blenrep 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 *Blenrep* combinations for the treatment of relapsed or refractory multiple myeloma in adult patients who have received at least one prior therapy.

Indication
In Japan, *Blenrep* is indicated for the treatment of adults with relapsed or refractory multiple myeloma.

IMPORTANT SAFETY INFORMATION FOR *BLENREP*
Please refer to the updated Product Information (PI) for precautions concerning indications, dosage and administration, and safety information in Japan which will shortly be updated at this link: Japan Pharmaceuticals and Medical Devices Agency.[18]

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. 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.

In DREAMM-7, BVd nearly tripled median PFS versus DVd (36.6 months versus 13.4 months, respectively (hazard ratio [HR]: 0.41 [95% confidence interval (CI): 0.31-0.53], p-value<0.00001). DREAMM-7 also met the key secondary endpoint of OS, showing a statistically significant and clinically meaningful 42% reduction in the risk of death at a median follow-up of 39.4 months favouring BVd (n=243) versus DVd (n=251) (HR 0.58; 95% CI: 0.43-0.79; p=0.00023). The three-year OS rate was 74% in the BVd arm and 60% in the DVd arm.

PFS results 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 were presented at the American Society of Hematology (ASH) Annual Meeting in December 2024.[2,4]

About DREAMM-8
DREAMM-8 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin in combination with pomalidomide plus dexamethasone (BPd) compared to bortezomib and pomalidomide plus dexamethasone (PVd) in patients with relapsed or 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. The trial included 302 participants who were randomised 1:1 to receive either BPd or PVd. 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, 78% were refractory to lenalidomide, 25% had prior daratumumab exposure and of those most were daratumumab refractory. Belantamab mafodotin was administered at a dose of 2.5mg/kg intravenously for the first cycle and 1.9mg/kg intravenously every four weeks. The primary endpoint was PFS as per an independent review committee, with key secondary endpoints including 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.

In DREAMM-8, a statistically significant and clinically meaningful improvement in PFS (HR: 0.52 [95% CI: 0.37-0.73], p-value<0.001) was observed with BPd (n=155) compared to PVd (n=147). At a median follow-up of 21.8 months, the median PFS was not yet reached (95% CI: 20.6-not yet reached [NR]) with BPd compared to 12.7 months (95% CI: 9.1-18.5) for PVd. At the end of one year, 71% (95% CI: 63-78) of patients in the BPd combination group compared to 51% (95% CI: 42-60) in the PVd combination group were alive and had not progressed. A benefit for BPd was observed across all pre-specified subgroups including those with poor prognostic features, such as patients who were refractory to lenalidomide and patients with high-risk cytogenetics. A positive OS trend was observed but not statistically significant (HR: 0.77 [95% CI: 0.53-1.14]) at the interim analysis. OS follow-up continues and further analyses are planned.

Results were first presented at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.[3]

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:	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:	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

---

[1] Nooka AK, Kastritis E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015;125(20). doi:10.1182/blood-2014-11-568923.
[2] 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.
[3] Dimopoulos MA, Beksac M, Pour L, Delimpasi S et al. Belantamab Mafodotin, Pomalidomide, and Dexamethasone in Multiple Myeloma. N Engl J Med. 2024 Aug 1;391(5):408-421. doi: 10.1056/NEJMoa2403407. Epub 2024 Jun 2. PMID: 38828951.
[4] 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.
[5] National Cancer Registry (Ministry of Health, Labour and Welfare), tabulated by Cancer Information Service, National Cancer Center, Japan. Available here: https://ganjoho.jp/reg_stat/statistics/data/dl/en.html. Accessed 12 September 2024.
[6] GSK data on file.
[7] GSK press release issued 25 November 2024. Blenrep combinations accepted for review by the US FDA for the treatment of relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-combinations-accepted-for-review-by-the-us-fda-for-the-treatment-of-relapsedrefractory-multiple-myeloma/.
[8] GSK press release issued 19 July 2024. Blenrep (belantamab mafodotin) combinations in multiple myeloma accepted for review by the European Medicines Agency. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combinations-in-multiple-myeloma-application-accepted-for-review-by-the-european-medicines-agency/.
[9] 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/.
[10] 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.
[11] 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.
[12] 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.
[13] Global Cancer Observatory. International Agency for Research on Cancer. World Health Organization. Age-Standardized Rate (World) per 100,000, Incidence, Both sexes, in 2022. Available at: https://gco.iarc.who.int/today/en/dataviz/bars?mode=population&cancers=35&populations=100_112_191_196_203_208_233_246_250_276_300_348_352_372_380_40_428_440_442_470_498_499_528_56_578_616_620_642_643_688_70_703_705_724_752_756_8_804_807_826&types=0&sort_by=value0. Accessed 5 March 2025.
[14] Ozaki S, Handa H, Saitoh T, et al. Trends of survival in patients with multiple myeloma in Japan: a multicenter retrospective collaborative study of the Japanese Society of Myeloma. Blood Cancer J. 2015 Sep 18;5(9):e349.
[15] Handa H, Ishida T, Ozaki S et al. Treatment pattern and clinical outcomes in multiple myeloma patients in Japan using the Medical Data Vision claims database. PLoS One. 2023 Apr 6;18(4):e0283931.
[16] Gajra A, Zalenski 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.
[17] 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.
[18] Japan Pharmaceuticals and Medical Devices Agency website: https://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html.