Stock-exchange announcement

For media and investors only

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

- Significant unmet need for patients requires new and novel treatments[1]
- 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 triplet[2]
- *Blenrep* is the only anti-BCMA accessible in the community setting where 70% of patients receive care, and with a new streamlined REMS program[3]
- Robust clinical development is ongoing to advance *Blenrep* in earlier lines of treatment, including newly diagnosed patients[4]

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 centers where 70% of patients receive care, *Blenrep* fulfills 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. For more information, resources, or assistance, visit www.BLENREPREMS.com or contact the *Blenrep* REMS at 1-855-690-9572, Monday–Friday, 8:00 AM–8:00 PM ET. GSK will also offer Together with GSK, an optional patient support program available to all US patients prescribed *Blenrep*. Designed to assist both patients and healthcare providers, the program offers personalized help navigating insurance, addressing cost concerns, and offering ongoing education and support. Learn more at TogetherwithGSK.com.

Data from the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical trial program 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."

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 program 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 enrollment 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 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 more than 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 center.[3,15,16]

About DREAMM-7
DREAMM-7 is a multicenter, open-label, randomized phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin-blmf 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 randomized 1:1 to receive either BVd or DVd. Belantamab mafodotin-blmf 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[17] 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[18] were presented at the American Society of Hematology (ASH) Annual Meeting in December 2024.

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

About *Blenrep* (belantamab mafodotin-blmf)
Blenrep is a monoclonal ADC (antibody-drug conjugate) comprising a humanized 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 and Important Safety Information for BLENREP (belantamab mafodotin-blmf)

BLENREP is indicated in combination with bortezomib and dexamethasone 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.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

WARNINGS AND PRECAUTIONS
Ocular Toxicity
BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

BLENREP Risk Evaluation and Mitigation Strategy (REMS)
BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

Thrombocytopenia
Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

Embryo-fetal Toxicity
Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.

ADVERSE REACTIONS
The most common adverse reactions (≥20%) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.

The most common Grade 3 or 4 (≥10%) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

Please see the full US Prescribing Information, including BOXED WARNING and Medication Guide for BLENREP.

GSK in oncology
Our ambition in oncology is to help increase overall quality of life, maximize 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 tumors. This includes accelerating priority programs 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 us.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 Q2 Results for 2025.

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[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.
[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, Kastritis 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, 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.

[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] 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/.
[18] 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/.