Stock-exchange announcement

For media and investors only

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Blenrep (belantamab mafodotin) combinations approved by UK MHRA in 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]
- UK approval first in the world with submissions under review in 14 markets and additional approvals expected in 2025

GSK plc (LSE/NYSE: GSK) today announced the authorisation of *Blenrep* by the Medicines and Healthcare products Regulatory Agency (MHRA). In the UK, *Blenrep* is approved for the treatment of adults with multiple myeloma in combination with bortezomib plus dexamethasone (BVd) in patients who have received at least one prior therapy, and in combination with pomalidomide plus dexamethasone (BPd) in patients who have received at least one prior therapy including lenalidomide. This UK regulatory authorisation marks the first in the world for *Blenrep* in this treatment setting.

Superior efficacy results from the pivotal DREAMM-7 and DREAMM-8 phase III trials in relapsed or refractory multiple myeloma support MHRA authorisation 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 of *Blenrep* combinations in the UK is a transformative milestone for patients with multiple myeloma, a cancer marked by remission and relapse. As the only BCMA-targeted ADC therapy, *Blenrep* has the potential, supported by robust phase III data, to extend survival and remission versus standard of care and redefine treatment at or after first relapse.”

Currently, most patients with multiple myeloma experience relapse, and in the UK only 55% remain alive five years after diagnosis.[5] *Blenrep* is the only anti-BCMA (B-cell maturation antigen) antibody-drug conjugate (ADC) 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.

Joseph Mikhael, MD, Chief Medical Officer, International Myeloma Foundation and Professor, Translational Genomics Research Institute, City of Hope Cancer Center, said: “As patients with multiple myeloma increasingly receive combination therapies at diagnosis, treatment options available in the community setting that use different mechanisms like *Blenrep* are crucial to extending remission and ultimately survival. We are pleased to see this advancement in the treatment landscape extended across both academic and community settings where many patients are treated.”

Both DREAMM-7 and DREAMM-8 showed statistically significant and clinically meaningful PFS improvements for the *Blenrep* combinations compared to standard of care triplet combinations in the second line or later treatment of multiple myeloma.[2,3] In DREAMM-7, the *Blenrep* combination nearly tripled median PFS versus the daratumumab-based comparator (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).[2] 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 the *Blenrep* combination (n=243) versus the daratumumab-based comparator (n=251) (HR 0.58; 95% CI: 0.43-0.79; p=0.00023).[4] The three-year OS rate was 74% in the *Blenrep* combination arm and 60% in the daratumumab combination arm. In DREAMM-8, at a median follow-up of 21.8 months, the median PFS was not yet reached with the *Blenrep* combination compared to 12.7 months in the bortezomib combination.[3]

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, a known side effect of treatment with *Blenrep*, were generally resolvable, manageable with extended time between infusions and dose reductions while maintaining efficacy, and led to low (≤9%) treatment discontinuations in both trials.[2,3] 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.

Blenrep combinations are currently under review in 14 countries, including in the US with a Prescription Drug User Fee Act (PDUFA) date of 23 July 2025,[6] European Union,[7] Japan (with priority review),[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.[12] Multiple myeloma is a significant concern in the UK, which ranks fifth in incidence rate of all European countries. There are approximately more than 6,500 new cases of multiple myeloma diagnosed each year and an expected 5-year prevalence of over 19,400 cases in the UK.[13,14] 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.[15,16]

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.

Indication
In the UK, *Blenrep* is indicated in adults for the treatment of multiple myeloma:

- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and
- in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide.

IMPORTANT SAFETY INFORMATION FOR *BLENREP*
More information can be found in the *Blenrep* Summary of Product Characteristics and Patient Information leaflets which will be published on the MHRA Products website within 7 days of approval.

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/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. Results were first presented at the American Society of Clinical Oncology (ASCO) Plenary Series in February 2024 and published in the *New England Journal of Medicine*.[2]

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

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.

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[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 Health Service. Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/cancer-survival-in-england/cancers-diagnosed-2016-to-2020-followed-up-to-2021/survival-by-cancer-group.
[6] 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/.
[7] 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/.
[8] GSK press release issued 17 September 2024. Blenrep (belantamab mafodotin) combinations in relapsed/refractory multiple myeloma accepted for regulatory review in Japan. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-combinations-in-relapsedrefractory-multiple-myeloma-accepted-for-regulatory-review-in-japan/.
[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] Global Cancer Observatory. International Agency for Research on Cancer. World Health Organization. United Kingdom fact sheet. Available at: https://gco.iarc.who.int/media/globocan/factsheets/populations/826-united-kingdom-fact-sheet.pdf. Accessed 5 March 2025.
[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.