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GSK announces extension of US Food and Drug Administration review period for *Blenrep* (belantamab mafodotin-blmf) in relapsed/refractory multiple myeloma

- New PDUFA date scheduled for October 23, 2025

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has extended the review period for the Biologics License Application (BLA) for *Blenrep (belantamab mafodotin-blmf)* combinations[1] for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy. The new Prescription Drug User Fee Act (PDUFA) action date is October 23, 2025 and provides the FDA with time to review additional information provided in support of the application.

The BLA is supported by efficacy results shown by *Blenrep* combinations in the pivotal DREAMM-7 and DREAMM-8 phase III trials in relapsed or refractory multiple myeloma. These include statistically significant and clinically meaningful progression-free survival results for *Blenrep* combinations versus triplet standard of care combinations in both trials and overall survival versus a daratumumab-based triplet in DREAMM-7. The safety and tolerability profiles of the *Blenrep* combinations were broadly consistent with the known profiles of the individual agents.

GSK is confident in the data supporting *Blenrep* combinations and looks forward to ongoing constructive conversations with the FDA as they continue their review.

Blenrep combinations are currently approved in the UK[2], Japan[3], Canada, Switzerland (DREAMM-8 only at this time) and the United Arab Emirates. Applications are currently under review in all major markets globally, including the EU[4] and China[5] (based on the results of DREAMM-7, with Breakthrough Therapy Designation for the combination and priority review for the application).

About multiple myeloma
Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[6,7] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[8] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[9] 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 center.[10,11]

About belantamab mafodotin-blmf
Belantamab mafodotin-blmf is an investigational ADC comprising a humanized 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.

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 progression-free survival (PFS) as per an independent review committee, with secondary endpoints including overall

survival (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), and safety.

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.[12,13]

About DREAMM-8
DREAMM-8 is a multicenter, open-label, randomized phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin-blmf 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 randomized 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-blmf was administered at a dose of 2.5mg/kg intravenously for the first cycle and then 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, and safety.

At the primary analysis 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 belantamab mafodotin-blmf in combination compared to 12.7 months in the bortezomib combination (95% CI: 9.1-18.5). 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.

With additional follow-up, a clinically meaningful benefit continued to be observed, with a near-tripling of the median PFS for the belantamab mafodotin-blmf combination versus the bortezomib combination (32.6 months versus 12.5 months, respectively (HR: 0.49 [95% CI: 0.35-0.68]). 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.

Results were first presented at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.[14] Updated PFS results were presented at European Hematology Association Congress (EHA) 2025.[15]

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 Q1 Results for 2025.

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[1]Belantamab mafodotin-blmf in combination with bortezomib plus dexamethasone (BVd) and belantamab mafodotin in combination with pomalidomide plus dexamethasone (BPd).
[2] GSK press release issued 17 April 2025. Blenrep (belantamab mafodotin-blmf) 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/.
[3] GSK press release issued 19 May 2025. Blenrep (belantamab mafodotin-blmf) 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/.
[4] GSK press release issued 19 July 2024. Blenrep (belantamab mafodotin-blmf) combinations in multiple myeloma application 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/.
[5] GSK press release issued 9 December 2024. Blenrep (belantamab mafodotin-blmf) 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/.
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[12] 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.
[13] 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.
[14] 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.
[15] Dimopoulos MA, Beksac M, Pour L et al. Updated results from phase 3 DREAMM-8 study of Belantamab Mafodotin, Pomalidomide and Dexamethasone versus Pomalidomide plus Bortezomib and Dexamethasone in relapsed/refractory multiple myeloma. HemaSphere | 2025;9(S1) 846 EHA 2025 Congress.