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Belantamab mafodotin combinations accepted for review by the US FDA for the treatment of relapsed/refractory multiple myeloma

- Regulatory submission supported by phase III head-to-head DREAMM-7 and DREAMM-8 trials showing statistically significant efficacy, including overall survival in DREAMM-7
- If approved, belantamab mafodotin in combinations with BorDex (BVd) and PomDex (BPd) could redefine multiple myeloma treatment at or after first relapse
- Sixth major regulatory filing acceptance this year for belantamab mafodotin combinations in this indication
- US decision expected by July 23, 2025

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for belantamab mafodotin in combinations with bortezomib plus dexamethasone (BorDex [BVd]) and pomalidomide plus dexamethasone (PomDex [BPd]) for the treatment of patients with multiple myeloma who have received at least one prior line of therapy. The US FDA has assigned a Prescription Drug User Fee Act action date of July 23, 2025.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Relapsed/refractory multiple myeloma treatment could be transformed by additional, efficacious treatment options with manageable side effects and community-based administration. The evidence from DREAMM-7 and DREAMM-8 supporting our belantamab mafodotin combinations submission has been further strengthened by the statistically significant overall survival results from the DREAMM-7 trial. We look forward to working with the FDA on this review."

The US application is based on results from the DREAMM-7 and DREAMM-8 phase III trials, which both met their primary endpoints, showing statistically significant and clinically meaningful improvements in progression-free survival (PFS) for the belantamab mafodotin combinations compared to standard of care triplet combinations in relapsed or refractory multiple myeloma.

Results from both trials also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses compared to the respective standard of care combinations. The safety and tolerability profiles of the belantamab mafodotin combinations in the DREAMM-7 and DREAMM-8 trials were broadly consistent with the known profiles of the individual agents.

In a subsequent planned interim analysis, the DREAMM-7 trial also met the key secondary endpoint of overall survival[1] (OS), showing a statistically significant and clinically meaningful OS benefit favoring the belantamab mafodotin combination. Efficacy and safety data from this analysis will be presented at the upcoming 66th American Society of Hematology (ASH) Annual Meeting and Exposition on December 9, 2024 at 11:15 a.m. PT. A positive trend in OS was observed in DREAMM-8 but was not statistically significant at the time of interim analysis, and follow-up for OS continues.

This is the sixth major regulatory filing acceptance this year for belantamab mafodotin combinations in the treatment of relapsed or refractory multiple myeloma based on the results of the DREAMM-7 and DREAMM-8 trials. In 2024, belantamab mafodotin combinations have been accepted for review in the European Union[2], Japan[3] (with priority

review), United Kingdom, Canada and Switzerland (with priority review for DREAMM-8). In China[4], the National Medical Products Administration has granted Breakthrough Therapy Designation for belantamab mafodotin in combination with bortezomib and dexamethasone, as well as priority review for the regulatory application based on the results of DREAMM-7.

About multiple myeloma
Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[5,6] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[7] Multiple myeloma is a significant and enduring health concern in the US, where more than 35,000 cases are expected to be diagnosed in 2024.[6,8] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[9]

About DREAMM-7
The DREAMM-7 phase III clinical trial is a multi-center, open-label, randomized trial evaluating the efficacy and safety of belantamab mafodotin in combination with bortezomib plus dexamethasone (BVd) compared to a combination of daratumumab and 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.

A total of 494 participants were randomized at a 1:1 ratio to receive either BVd or DVd. Belantamab mafodotin was scheduled to be dosed at 2.5mg/kg intravenously every three weeks.

The primary endpoint is PFS as per an independent review committee. The key secondary endpoints include 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 from DREAMM-7 were first presented[10] at the American Society of Clinical Oncology (ASCO) Plenary Series in February 2024, shared in an encore presentation at the 2024 ASCO Annual Meeting, and published in the *New England Journal of Medicine*.

About DREAMM-8
The DREAMM-8 phase III clinical trial is a multi-center, open-label, randomized trial evaluating the efficacy and safety of belantamab mafodotin in combination with pomalidomide plus dexamethasone (BPd) compared to a combination of 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. 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.

A total of 302 participants were randomized at a 1:1 ratio to receive either BPd or PVd.

The primary endpoint is PFS as per an independent review committee. The key secondary endpoints include 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 from DREAMM-8 were first presented[11] at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.

About belantamab mafodotin
Belantamab mafodotin is an investigational antibody-drug conjugate comprising a humanized B-cell maturation antigen 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.

GSK in oncology
Oncology is an emerging therapeutic area for GSK where we are committed to maximizing patient survival with a current focus on hematologic malignancies, gynecologic cancers, and other solid tumors through breakthroughs in immuno-oncology and tumor-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 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 under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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[1] GSK press release issued 14 November 2024. Blenrep shows overall survival benefit in head-to-head DREAMM-7 phase III trial for relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-shows-overall-survival-benefit-in-head-to-head-dreamm-7-phase-iii-trial-for-relapsedrefractory-multiple-myeloma/.
[2] 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/.
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[4] GSK press release issued 13 September 2024. Blenrep (belantamab mafodotin) in combination receives Breakthrough Therapy Designation in China for treatment of relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-belantamab-mafodotin-in-combination-receives-breakthrough-therapy-designation-in-china-for-treatment-of-relapsedrefractory-multiple-myeloma/.
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[8] American Cancer Society Cancer Statistics Center. Myeloma. https://cancerstatisticscenter.cancer.org/#!/cancer-site/Myeloma. Accessed April 2024.
[9] Nooka AK, Kastritis E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015;125(20).
[10] 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/.
[11] GSK press release issued 02 June 2024. Blenrep combination reduced the risk of disease progression or death by nearly 50% versus standard of care combination in relapsed/refractory multiple myeloma Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-combination-reduced-the-risk-of-disease-progression/.