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Belantamab mafodotin shows overall survival benefit in head-to-head DREAMM-7 phase III trial for relapsed/refractory multiple myeloma

- Statistically significant and clinically meaningful reduction in the risk of death seen with belantamab mafodotin plus bortezomib and dexamethasone (BorDex) versus daratumumab plus BorDex
- Full data to be presented at 2024 American Society of Hematology Annual Meeting in December
- Data to be shared with health authorities to support regulatory filings

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GSK plc (LSE/NYSE: GSK) today announced positive headline results from a planned interim analysis of the DREAMM-7 head-to-head phase III trial evaluating belantamab mafodotin in combination with bortezomib plus dexamethasone (BorDex) as a second-line or later treatment for relapsed or refractory multiple myeloma. The trial met the key secondary endpoint of overall survival (OS), showing that belantamab mafodotin when combined with BorDex significantly reduced the risk of death versus standard of care daratumumab plus BorDex.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "The overall survival results from the DREAMM-7 trial underscore the potential for this belantamab mafodotin combination to extend the lives of patients with relapsed/refractory multiple myeloma. This is a statistically significant and clinically meaningful advancement for patients and potentially transformative for treatment. We look forward to sharing these data with health authorities and presenting the full results at next month's American Society of Hematology Annual Meeting."

Results from the interim analysis, including safety data, 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.

The DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical development program continues to evaluate the potential of belantamab mafodotin in early lines of treatment and in combination with novel therapies and standard of care treatments. In addition to DREAMM-7, this includes the ongoing head-to-head phase III DREAMM-8 trial evaluating belantamab mafodotin in combination with pomalidomide and dexamethasone versus bortezomib in combination with pomalidomide and dexamethasone.

A phase III study in newly diagnosed transplant ineligible multiple myeloma is expected to be initiated by the end of 2024 as part of the DREAMM program.

In 2024, belantamab mafodotin combinations have been filed in the US, European Union[1], Japan[2], United Kingdom, Canada and Switzerland for the treatment of relapsed or refractory multiple myeloma based on the results of the DREAMM-7 and DREAMM-8 trials. In China[3], the National Medical Products Administration has granted Breakthrough Therapy Designation for belantamab mafodotin in combination with BorDex, as well as priority review for the regulatory application based on the results of DREAMM-7.

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 BorDex compared to a combination of daratumumab and

BorDex 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 belantamab mafodotin in combination with BorDex or a combination of daratumumab and BorDex. 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[4] 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 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] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[8]

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 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 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/.
[2] 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/.
[3] 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/.
[4] 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/.
[5] 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.
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[8] Nooka AK, Kastritis E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015;125(20).