GSK announces positive results from DREAMM-8 phase III trial for Blenrep versus standard of care combination in relapsed/refractory multiple myeloma

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For media and investors only

- Trial unblinded early at an interim analysis based on Independent Data Monitoring Committee recommendation

- Blenrep (belantamab mafodotin) plus PomDex showed statistically significant and clinically meaningful progression-free survival compared to bortezomib plus PomDex

- Consistent efficacy results observed for Blenrep combinations in two phase III head-to-head trials

GSK plc (LSE/NYSE: GSK) today announced positive headline results from an interim analysis of the DREAMM-8 phase III head-to-head trial evaluating Blenrep (belantamab mafodotin), in combination with pomalidomide plus dexamethasone (PomDex), versus a standard of care, bortezomib plus PomDex, as a second line and later treatment for relapsed or refractory multiple myeloma. The trial met its primary endpoint of progression-free survival (PFS) at a pre-specified interim analysis and was unblinded early based on the recommendation by an Independent Data Monitoring Committee (IDMC).

The belantamab mafodotin combination significantly extended the time to disease progression or death versus the standard of care combination. A positive overall survival (OS) trend favouring the Blenrep combination was also observed at the time of this analysis. The trial continues to follow up for OS. The safety and tolerability of

the belantamab mafodotin regimen were broadly consistent with the known safety profile of the individual agents.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said:

> The results seen in both DREAMM-7 and DREAMM-8 provide strong clinical evidence of the robust efficacy shown with belantamab mafodotin in use with standard of care combinations. We now look forward to discussing these data with regulators. If approved, we believe these combinations have the potential to redefine the treatment of relapsed or refractory multiple myeloma and advance the standard of care. This is exciting news for patients given the high unmet medical need for both efficacious and easily administered therapies with differing mechanisms of action.

DREAMM-8 is the second phase III head-to-head belantamab mafodotin combination trial in second line and later treatment for multiple myeloma to report positive results. Positive findings from DREAMM-7, a phase III head-to-head trial evaluating belantamab mafodotin in combination with bortezomib and dexamethasone (BorDex) versus daratumumab plus BorDex in the same treatment setting, were presented 1 at the American Society of Clinical Oncology (ASCO) Plenary Series on 6 February 2024. Detailed findings from DREAMM-8 will be presented at a future medical congress and shared with regulatory authorities.

The DREAMM-8 phase III clinical trial is a multicentre, open-label, randomised trial evaluating the efficacy and safety of belantamab mafodotin in combination with PomDex compared to a combination of bortezomib and PomDex 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.

A total of 302 participants were randomised at a 1:1 ratio to receive either belantamab mafodotin plus PomDex, or bortezomib plus PomDex.

The primary endpoint is PFS. Secondary endpoints include OS, overall response rate, duration of response, minimal residual disease

negativity as assessed by next-generation sequencing, safety, and patient-reported and quality of life outcomes.

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.2,3 There are approximately 176,000 new cases of multiple myeloma diagnosed globally each year.4 Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.5

Blenrep is an antibody-drug conjugate comprising a humanised 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.

Refer to the Blenrep UK Summary of Product Characteristics 6 for a full list of adverse events and the complete important safety information in the United Kingdom.

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.

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.

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 the company's Annual Report on Form 20-F for 2023.

This announcement contains inside information. The person responsible for arranging the release of this announcement on behalf of GSK is Victoria Whyte, Company Secretary.

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-... 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. 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. Multiple Myeloma: Statistics. Cancer.net. Published February 2022. https://www.cancer.net/cancer-types/multiple-myeloma/statistic.... Accessed 19 October 2023. Nooka AK, Kastritis E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015;125(20). Blenrep UK Summary of Product Characteristics, available at: https://mhraproducts4853.blob.core.windows.net/docs/6f7040d4dd....

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