GSK provides an update on Blenrep (belantamab mafodotin-blmf) US marketing authorisation

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For media and investors only

GSK plc (LSE/NYSE: GSK) today announced it has initiated the process for withdrawal of the US marketing authorisation for Blenrep (belantamab mafodotin-blmf) following the request of the US Food and Drug Administration (FDA). This request was based on the previously announced outcome of the DREAMM-3 phase III confirmatory trial, which did not meet the requirements of the FDA Accelerated Approval regulations. Blenrep is a monotherapy treatment for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

As part of the Company's efforts to ensure physicians and patients are supported during this important time, patients already enrolled in the Blenrep Risk Evaluation and Mitigation Strategy (REMS) programme will have the option to enrol in a compassionate use programme to continue to access treatment. Further information on how to enrol patients into the compassionate use program will be provided directly to REMS enrolled prescribers. Patients currently being treated with Blenrep should consult their healthcare provider.

GSK continues to believe, based on the totality of data available from the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) development programme, that the benefit-risk profile of belantamab mafodotin remains favourable in this hard-to-treat RRMM patient population. Patients responding to belantamab mafodotin experienced durable clinical benefit, and safety remains consistent with the known safety profile.

Sabine Luik, Chief Medical Officer, said,

> We respect the Agency's approach to the accelerated approval

regulations and associated process. Multiple myeloma is a challenging disease, with poor outcomes for patients whose disease has become resistant to standard-of-care treatments. We will continue the DREAMM clinical trial programme and work with the US FDA on a path forward for this important treatment option for patients with multiple myeloma.

Additional trials within the DREAMM clinical trial programme are designed to determine the benefit of belantamab mafodotin in combination treatment with novel therapies and standard-of-care treatments in earlier lines of therapy and dosing optimisation to maintain efficacy while reducing corneal events. Data from the DREAMM-7 and DREAMM-8 phase III trials are event-driven, and results are anticipated in the first half of 2023. Results of these trials will be shared with health authorities and inform future regulatory pathways.

The DREAMM-3 phase III trial is an open-label, randomised head-to-head superiority trial evaluating the efficacy and safety of single-agent belantamab mafodotin compared to pomalidomide in combination with low-dose dexamethasone (PomDex) in patients with RRMM. A total of 325 participants were randomised in a 2:1 ratio to receive either single-agent belantamab mafodotin administered as a 2.5 mg/kg dose every three weeks or PomDex. Pomalidomide was administered daily on days 1 to 21 of each 28-day cycle, with dexamethasone administered once weekly (days 1, 8, 15, and 22 of each cycle). The primary endpoint was PFS. Secondary endpoints include overall survival, safety, ORR, duration of response and assessment of minimal residual disease.

DREAMM-7 is evaluating the safety and efficacy of belantamab mafodotin in combination with bortezomib and dexamethasone versus daratumumab in combination with bortezomib and dexamethasone.

DREAMM-8 is assessing the efficacy and safety of belantamab mafodotin in combination with pomalidomide and dexamethasone compared with that of a combination of pomalidomide, bortezomib and dexamethasone in participants with relapsed/refractory multiple myeloma.

Multiple myeloma is the second most common blood cancer in the US and is generally considered treatable but not curable. 1, 2 In the US, more than 32,000 people are estimated to be diagnosed with multiple

myeloma this year, and nearly 13,000 people will die from the disease. 3 Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments. 4

About B-cell maturation antigen (BCMA)

The normal function of BCMA is to promote plasma cell survival by transduction of signals from two known ligands, BAFF (B-cell activating factor) and APRIL (a proliferation-inducing ligand). This pathway is important for myeloma cell growth and survival. BCMA expression is limited to B cells at later stages of development. BCMA is expressed at varying levels in myeloma patients, and BCMA membrane expression is universally detected in myeloma cell lines. 5

Blenrep is an antibody-drug conjugate 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.

Refer to the BLENREP Prescribing Information for a full list of adverse events and the complete important safety information in the US.

GSK is focused on maximising patient survival through transformational medicines. GSK's pipeline is focused on immuno-oncology, tumour cell targeting therapies and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, and antibody-drug conjugates, either alone or in combination.

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/company

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 Company's

Annual Report on Form 20-F for 2021, GSK's Q3 Results for 2022 and any impacts of the COVID-19 pandemic.

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