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

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- 59% reduction in risk of disease progression or death observed in patients with Blenrep combination versus standard of care daratumumab combination

- 36.6 months of median progression-free survival observed with Blenrep combination versus 13.4 months in daratumumab combination

- Strong, clinically meaningful trend in overall survival favouring Blenrep combination was observed with 43% reduction in risk of death

GSK plc (LSE/NYSE: GSK) today announced results from an interim analysis of the DREAMM-7 phase III head-to-head trial evaluating Blenrep (belantamab mafodotin) combined with bortezomib plus dexamethasone (BorDex) versus daratumumab plus BorDex in second-line and later treatment of relapsed or refractory multiple myeloma. These data will be presented at the American Society of Clinical Oncology (ASCO) Plenary Series on 6 February 2024.

In the primary endpoint of progression-free survival (PFS), a statistically significant and clinically meaningful improvement was observed with the belantamab mafodotin combination (n=243), showing a 59% reduction in the risk of disease progression or death (hazard ratio [HR]: 0.41 [95% confidence interval (CI): 0.31-0.53], p-

value

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

> The substantial progression-free survival benefit and strong overall survival trend compared to a daratumumab standard of care combination reinforce our belief in the potential for belantamab mafodotin used in combination to redefine the treatment of multiple myeloma at or after first relapse. We plan on sharing these results with health authorities worldwide.

The belantamab mafodotin combination also resulted in clinically meaningful improvements in all secondary efficacy endpoints including a doubling of complete response rate (stringent complete response plus complete response), minimal residual disease (MRD) negativity rate and median duration of response (DOR). A strong and clinically meaningful overall survival (OS) trend was observed at the interim analysis, with a 43% reduction in the risk of death (HR: 0.57 [95% CI: 0.40-0.80], p-value=0.00049), which has not yet reached the interim criteria for statistical significance of OS. OS follow-up continues and further analyses are planned.

María-Victoria Mateos, MD, PhD, Head of Myeloma and Clinical Trials Unit, Haematology Department and Professor of Medicine at the University of Salamanca, Spain, and DREAMM-7 principal investigator, said:

> These results from DREAMM-7 show how belantamab mafodotin in combination with BorDex represents a significant improvement over the daratumumab-based regimen in a second-line multiple myeloma treatment setting. Anti-BCMA therapies are helping to improve outcomes for patients with multiple myeloma, and having an off-the-shelf option, like belantamab mafodotin, that can be administered in a community oncology treatment centre where the majority of patients are treated has the potential to transform the way we treat myeloma at or after first relapse.

Key secondary endpoint summaries are listed below.

Key Secondary Endpoints Endpoint belantamab mafodotin + BorDex

OOR (overall response rate) (95% CI) 82.7% (77.4-87.3) 71.3% (65.3-76.8) sCR (stringent complete response) 14.0% 5.2% CR (complete response) 20.6% 12.0% Very good partial response 31.3% 29.1% Partial response 16.9% 25.1% MRD negativity rate*

24.7 (19.4, 30.6) 9.6 (6.2, 13.9) p

* Measured in patients with a sCR or CR.

** An Intent-to-treat restricted mean DOR (RMDoR) analysis comparing DOR between arms showed a statistically significant benefit in favour of the belantamab mafodotin combination (p

*** Has not yet reached criteria for statistical significance ($p \leq 0.00037$) of OS at this interim. Follow-up for OS is ongoing.

Grade 3 or higher non-ocular adverse events of clinical interest in the belantamab mafodotin combination and daratumumab combination arms, respectively, included thrombocytopenia (55% and 35%; exposure-adjusted event rate: 40 and 29, per 100 person-years), neutropenia (12% and 6%), pneumonia (12% and 4%; exposure-adjusted event rate: 8 and 3, per 100 person-years), and anaemia (8% and 10%).

Eye-related side effects, a known risk of treatment with belantamab mafodotin, were generally reversible, manageable with dose modification, and led to low (9%) treatment discontinuations. Grade 3 or higher ocular adverse events occurred in 34% of patients receiving the belantamab mafodotin combination and primarily included blurred vision (22%), dry eye (7%), eye irritation (5%), and visual impairment (5%). Eighty-two patients (34%) with a best corrected visual acuity (BCVA) score of 20/25 or better in at least one eye at baseline had a worsening in both eyes to 20/50 or worse. Almost all these patients' events (98%) had resolved at the time of this analysis. The median time to resolution was 22 days.

Global health status quality of life (QOL) as measured by the EORTC-QLQ-C30 indicated no difference in global QOL between different treatment arms over time.

The DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical development programme continues to evaluate the potential of belantamab mafodotin in early lines of treatment and in

combination with novel therapies and standard of care treatments. This includes the ongoing phase III DREAMM-8 trial evaluating belantamab mafodotin in combination with pomalidomide and dexamethasone versus bortezomib in combination with pomalidomide and dexamethasone. DREAMM-8 data are expected in the second half of 2024.

The DREAMM-7 phase III clinical trial is a multicentre, open-label, randomised trial evaluating the efficacy and safety of belantamab mafodotin in combination with bortezomib and dexamethasone (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 randomised 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, DOR, and MRD negativity rate as assessed by next-generation sequencing.

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.1,2 There are approximately 176,000 new cases of multiple myeloma diagnosed globally each year.3 Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.4

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 EMA Reference Information (https://www.ema.europa.eu/en/medicines/human/EPAR/blenrep) for a full list of adverse events and the complete important safety information in the EU.

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 2022, and Q4 Results for 2023.

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