Stock-exchange announcement
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Blenrep (belantamab mafodotin) in combination receives Breakthrough Therapy Designation in China for treatment of relapsed/refractory multiple myeloma

- Granted based on results from phase III head-to-head DREAMM-7 trial
- Designation expedites development of investigational drugs with potential for substantial improvement over available therapies
- Novel therapies needed in multiple myeloma as patients typically relapse or stop responding to initial treatments[1]

GSK plc (LSE/NYSE: GSK) today announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China has granted Breakthrough Therapy Designation (BTD) for *Blenrep* (belantamab mafodotin) combined with bortezomib plus dexamethasone (BorDex) for the treatment of relapsed or refractory multiple myeloma. NMPA BTD is intended to expedite the development of therapies for serious and life-threatening diseases for which there are no existing treatments or where initial evidence has shown an improvement in patient outcomes over available treatment options.[2]

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Breakthrough Therapy Designation in China underscores the potential for *Blenrep* to redefine outcomes for patients with multiple myeloma at or after their first relapse. We look forward to continuing to work with the health authority in China and others worldwide to bring *Blenrep*-based combinations to patients as expeditiously as possible."

BTD was granted based on the interim results of the phase III head-to-head DREAMM-7 trial, which met its primary endpoint, showing statistically significant and clinically meaningful improvements in progression-free survival (PFS) for belantamab mafodotin combined with BorDex compared to daratumumab plus BorDex in relapsed or refractory multiple myeloma.

A positive overall survival (OS) trend was observed but was not statistically significant at the time of interim analysis. Follow-up for OS continues. Results also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses compared to the standard of care combination. The safety and tolerability profile of the belantamab mafodotin combination in the DREAMM-7 trial was broadly consistent with the known profiles of the individual agents.

Multiple myeloma is a growing health concern in China with approximately 30,000 new cases each year[3]. The incidence in China has doubled and mortality has increased 1.5-fold in the past three decades.[4] This underscores the need for novel, efficacious treatment options for patients in China, particularly those with progressing disease that has become resistant to the current standard of care.

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 DREAMM-7
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 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, 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[9] 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 *Blenrep*
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.

Blenrep is approved as monotherapy in Hong Kong, Israel and Singapore. Refer to the local Summary of Product Characteristics for a full list of adverse events and complete important safety information.

GSK in oncology
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.

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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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 Q2 Results for 2024.

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[9] 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/. Accessed 12 September 2024.