Stock-exchange announcement
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Blenrep (belantamab mafodotin) combinations in relapsed/refractory multiple myeloma accepted for regulatory review in Japan

- Regulatory submission supported by phase III head-to-head DREAMM-7 and DREAMM-8 trials
- If approved, *Blenrep* plus BorDex or PomDex could redefine relapsed/refractory multiple myeloma treatment landscape
- More than 7,200 new cases of multiple myeloma are diagnosed in Japan each year[1]

GSK plc (LSE/NYSE: GSK) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has accepted for review a new drug application (NDA) for *Blenrep* (belantamab mafodotin) in combination with bortezomib plus dexamethasone (BorDex) or pomalidomide plus dexamethasone (PomDex) as a treatment for relapsed or refractory multiple myeloma. MHLW also has granted orphan drug designation for *Blenrep*, which reflects the high unmet medical need and ensures priority NDA review in multiple myeloma.

This is the third major regulatory filing acceptance for belantamab mafodotin combinations in the treatment of relapsed/refractory multiple myeloma, following marketing authorisation application acceptance[2] by the European Medicines Agency (EMA) in July 2024 and by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK earlier this month.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "*Blenrep* combinations show potential based on the results of the DREAMM-7 and DREAMM-8 trials to redefine the treatment of relapsed/refractory multiple myeloma. We are committed to working with health authorities worldwide to advance *Blenrep* along regulatory pathways so we can bring these additional treatment options to patients as quickly as possible."

Multiple myeloma presents a growing health concern in Japan, where the number of patients diagnosed with multiple myeloma per year has increased continuously over the last five decades.[3,4] This underscores the urgent need for more treatment options for patients in Japan, particularly those with progressing disease that has become resistant to the current standard of care.

The application is based on interim results from the DREAMM-7 and DREAMM-8 phase III trials, which both met their primary endpoints, showing statistically significant and clinically meaningful improvements in progression-free survival (PFS) for the belantamab mafodotin combinations compared to standard of care combinations in relapsed or refractory multiple myeloma. A positive overall survival (OS) trend was observed in both trials but was not statistically significant at the time of interim analysis. Follow-up for OS continues. The DREAMM-7 trial is evaluating belantamab mafodotin combined with BorDex versus daratumumab plus BorDex, while the DREAMM-8 trial is evaluating belantamab mafodotin in combination with PomDex versus bortezomib plus PomDex.

Results from both trials also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses compared to the respective standard of care combinations. The safety and tolerability profiles of the belantamab mafodotin combinations in DREAMM-7 and DREAMM-8 trials were broadly consistent with the known profiles of the individual agents.

About multiple myeloma

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[1,5] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[6] More than 7,200 new cases of multiple myeloma are diagnosed in Japan each year.[1] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[7]

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, including Japanese patients, 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[8] 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*.

A Japan expansion cohort is set to further evaluate the DREAMM-7 protocol in Japanese patients. Results for Japanese participants will be presented at a future scientific meeting.

About DREAMM-8
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. Compared to the patient population studied in the DREAMM-7 trial, patients in DREAMM-8 were more heavily pre-treated in that all had prior exposure to lenalidomide, 75% were refractory to lenalidomide, 25% had prior daratumumab exposure and of those most were daratumumab refractory.

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

The primary endpoint is PFS as per an independent review committee. The key secondary endpoints include OS and MRD negativity rate as assessed by next-generation sequencing. Other secondary endpoints include ORR, DOR, safety, and patient reported and quality of life outcomes.

Results from DREAMM-8 were first presented[9] at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.

A Japan expansion cohort is set to further evaluate the DREAMM-8 protocol in Japanese patients. Results for Japanese participants will be presented at a future scientific meeting.

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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