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Blenrep (belantamab mafodotin) combinations approved in EU for treatment of relapsed/refractory multiple myeloma

- Two head-to-head phase III trials demonstrated superior efficacy, including overall survival versus a daratumumab-based triplet in DREAMM-7
- *Blenrep*, a first-in-class anti-BCMA ADC, could transform treatment as early as first relapse where additional effective and accessible options are needed[1],[2],[3]
- Sixth regulatory approval for *Blenrep* combinations with applications under review in all major markets

GSK plc (LSE/NYSE: GSK) today announced the approval of *Blenrep* in the European Union (EU) for the treatment of adults with relapsed or refractory multiple myeloma in combination with bortezomib plus dexamethasone (BVd) in patients who have received at least one prior therapy, and in combination with pomalidomide plus dexamethasone (BPd) in patients who have received at least one prior therapy including lenalidomide.

The approval is based on superior efficacy results demonstrated by *Blenrep* combinations in the pivotal DREAMM-7 and DREAMM-8 phase III trials in relapsed or refractory multiple myeloma. These include statistically significant and clinically meaningful progression-free survival (PFS) for *Blenrep* combinations versus triplet standard of care combinations in both trials and overall survival (OS) versus a daratumumab-based triplet in DREAMM-7.[2,3,4] The safety and tolerability profiles of the *Blenrep* combinations were broadly consistent with the known profiles of the individual agents.[2,3]

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Today's approval of *Blenrep* combinations is a redefining moment for patients with relapsed or refractory multiple myeloma in the EU. *Blenrep* has the potential to extend remission and survival, with superior efficacy versus standards of care in our DREAMM clinical trial programme and the option to administer in both academic and community-based settings."

More than 50,000 cases of multiple myeloma are diagnosed in Europe each year, accounting for more than a quarter of global incidence.[5] *Blenrep* is the only anti-BCMA (B-cell maturation antigen) antibody-drug conjugate (ADC) approved in multiple myeloma, providing patients with a differentiated mechanism of action to potentially help slow disease progression and extend survival.[1] *Blenrep* combinations can be administered to a range of patient types across oncology treatment settings, enabling broad accessibility of an anti-BCMA therapy.

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: "With the approval of *Blenrep* combinations in the EU, we now have additional tools in our efforts to keep patients in remission longer, maintain quality of life and extend survival. The robust efficacy supported by the DREAMM-7 and DREAMM-8 trials, together with manageable outpatient administration in academic and community settings, positions *Blenrep* combinations as a fundamentally differentiated treatment approach for multiple myeloma patients starting from first relapse."

Both DREAMM-7 and DREAMM-8 showed statistically significant and clinically meaningful PFS improvements for the *Blenrep* combinations compared to standard of care triplet combinations in the second line or later treatment of multiple myeloma.[2,3] In DREAMM-7, the *Blenrep* combination (n=243) nearly tripled median PFS versus the daratumumab-based comparator (n=251) (36.6 months versus 13.4 months, respectively (hazard ratio [HR]: 0.41 [95% confidence interval (CI): 0.31-0.53], p-value<0.00001).[2] DREAMM-7 also met the key secondary endpoint of OS, showing a statistically significant and clinically meaningful 42% reduction in the risk of death at a median follow

OS, showing a statistically significant and clinically meaningful 42% reduction in the risk of death at a median follow-up of 39.4 months favouring the *Blenrep* combination versus the daratumumab-based comparator (HR: 0.58; 95% CI: 0.43-0.79; p=0.00023). The median OS was not reached in either arm of the study. The three-year OS rate was 74% in the *Blenrep* combination arm and 60% in the daratumumab combination arm.[4] In DREAMM-8, at a median follow-up of 21.8 months, the median PFS was not yet reached (95% CI: 20.6-not yet reached [NR]) with the *Blenrep* combination compared to 12.7 months in the bortezomib combination (95% CI: 9.1-18.5) at the time of primary analysis.[3]

Blenrep combinations consistently benefited a broad range of patients, including those with poor prognostic features or outcomes, such as high-risk cytogenetics or those refractory to lenalidomide. Both trials also showed clinically meaningful improvements across all other secondary efficacy endpoints, including deeper and more durable responses versus the respective comparators.[2,3]

DREAMM-7 and DREAMM-8 showed that eye-related side effects associated with *Blenrep* can be managed and reversed with appropriate dose modifications and follow-up. This allowed patients to maintain benefit and resulted in low rates of discontinuation due to eye-related side effects (≤9%) in both trials.[2,3] The most commonly reported non-ocular adverse events (>30% of participants) in the *Blenrep* combination arm were thrombocytopenia (87%) and diarrhoea (32%) in DREAMM-7, and neutropenia (63%), thrombocytopenia (55%) and COVID-19 (37%) in DREAMM-8.[2,3]

Blenrep combinations are also approved in relapsed or refractory multiple myeloma in the UK[6] and Japan[7] as well as other markets, including Canada and Switzerland (based on the results of DREAMM-8). Applications are currently under review in all major markets globally, including the US[8] and China[9] (based on the results of DREAMM-7, with Breakthrough Therapy Designation for the combination and priority review for the application).

About multiple myeloma

Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[10],[11] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[5] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[1] Many patients with multiple myeloma are treated in a community cancer setting, leaving an urgent need for new, effective therapies with manageable side effects that can be administered outside of an academic centre.[12],[13]

About *Blenrep*

Blenrep is an ADC 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.

Indication

In the EU, *Blenrep* is indicated in adults for the treatment of relapsed or refractory multiple myeloma:

- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and
- in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide.

IMPORTANT SAFETY INFORMATION FOR *BLENREP*

Refer to the *Blenrep* EMA Reference Information[14] which will soon be available for a full list of adverse events and the complete important safety information in the EU.

About DREAMM-7

DREAMM-7 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin combined with bortezomib plus dexamethasone (BVd) compared to daratumumab combined with bortezomib plus dexamethasone (DVd) in patients with relapsed or 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. The trial enrolled 494 participants who were randomised 1:1 to receive either BVd or DVd. Belantamab mafodotin was administered at a dose of 2.5mg/kg intravenously every three weeks in combination for the first eight cycles and then continued as a single agent. The primary endpoint was PFS as per an independent review committee, with secondary endpoints including 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.

PFS results were presented at the American Society of Clinical Oncology (ASCO) Plenary Series in February 2024 and published in the *New England Journal of Medicine*. OS results were presented at the American Society of Hematology (ASH) Annual Meeting in December 2024.[2,4]

About DREAMM-8

DREAMM-8 is a multicentre, open-label, randomised phase III clinical trial evaluating the efficacy and safety of belantamab mafodotin in combination with pomalidomide plus dexamethasone (BPd) compared to bortezomib and pomalidomide plus dexamethasone (PVd) in patients with relapsed or 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. The trial included 302 participants who were randomised 1:1 to receive either BPd or PVd. 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, 78% were refractory to lenalidomide, 25% had prior daratumumab exposure and of those most were daratumumab refractory. Belantamab mafodotin was administered at a dose of 2.5mg/kg intravenously for the first cycle and then 1.9mg/kg intravenously every four weeks. The primary endpoint was PFS as per an independent review committee, with key secondary endpoints including 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 were first presented at the 2024 ASCO Annual Meeting and published in the *New England Journal of Medicine*.[3] Updated PFS results were presented at the European Hematology Association (EHA) Congress in June 2025.[15]

GSK in oncology

Our ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates targeting B7-H3 and B7-H4, and IDRX-42, a highly selective KIT tyrosine kinase inhibitor.

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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