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Belantamab Mafodotin shows significant overall survival benefit, reducing the risk of death by 42% in multiple myeloma at or after first relapse

- DREAMM-7 trial shows sustained overall survival benefit for belantamab mafodotin combination versus daratumumab combination; benefit seen early and maintained through follow-up
- Data build on findings from DREAMM-7 and DREAMM-8 and support the potential for belantamab mafodotin combinations to become standard of care
- Belantamab mafodotin combinations are under regulatory review in seven major markets

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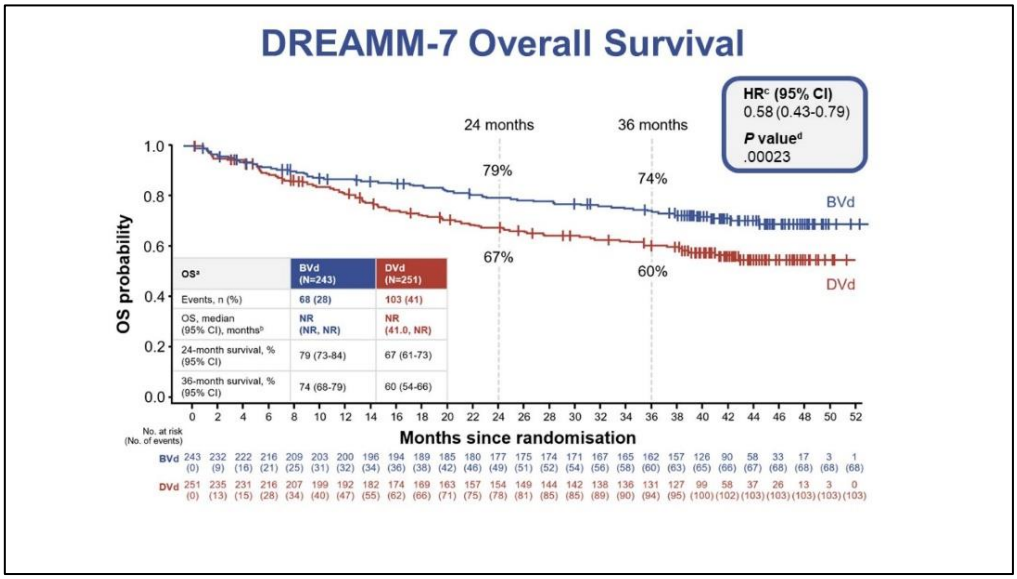
GSK plc (LSE/NYSE: GSK) today announced statistically significant and clinically meaningful overall survival (OS) results from a planned interim analysis of the DREAMM-7 trial evaluating belantamab mafodotin in combination with bortezomib plus dexamethasone (BVd) versus daratumumab in combination with bortezomib plus dexamethasone (DVd) as a second line or later treatment for relapsed or refractory multiple myeloma. These data were featured today in an oral presentation at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition.

The OS findings from DREAMM-7 build on previous data from the DREAMM-7[1] and DREAMM-8[2] trials, which showed a statistically significant and clinically meaningful improvement in progression-free survival (PFS) for both belantamab mafodotin-based combinations versus standard of care comparators.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: “The compelling overall survival data from the DREAMM-7 trial establish the potential of belantamab mafodotin in combination to significantly extend the lives of patients with multiple myeloma at or after first relapse. This represents an important advancement that could redefine the treatment of relapsed or refractory multiple myeloma.”

With a median follow up of 39.4 months, the analysis presented today shows a statistically significant 42% reduction in the risk of death among patients receiving the belantamab mafodotin combination (n=243) versus the daratumumab-based comparator (n=251) (HR 0.58; 95% CI: 0.43-0.79; p=0.00023). Although the median overall survival (mOS) was not reached in either arm of the study, the projected mOS for BVd is 84 months compared to 51 months for DVd.[3]

The three-year OS rate was 74% in the belantamab mafodotin combination arm and 60% in the daratumumab combination arm. The survival benefit favoring BVd was seen as early as four months and was sustained over time as illustrated by the separation of the lines in the Kaplan-Meier curve shown here.



BVd, belantamab mafodotin, bortezomib, and dexamethasone; DVd, daratumumab, bortezomib, and dexamethasone; HR, hazard ratio; ITT, intention to treat; NR, not reached; OS, overall survival; R-ISS, Revised International Staging System.

[a] Two patients in the ITT population were randomized, not treated, rescreened, and rerandomized. They are counted as 4 unique patients in this output.
[b] CIs were estimated using the Brookmeyer-Crowley method.
[c] HRs were estimated using a Cox proportional hazards model stratified by the number of lines of prior therapy (1 vs 2 or 3 vs ≥4), prior bortezomib (no vs yes), and R-ISS stage at screening (I vs II or III), with a covariate of treatment.
[d] *P* value is from a 1-sided stratified log-rank test. At 171 actual events (48.2% OS information fraction), OS was declared significant if the *P* value was <.00112.

María-Victoria Mateos, MD, PhD, Head of Myeloma and Clinical Trials Unit, Hematology Department and Professor of Medicine at the University of Salamanca, Spain, and DREAMM-7 principal investigator, said: "The totality of evidence from DREAMM-7 represents a potential paradigm shift for multiple myeloma patients who have experienced a relapse or become refractory to initial treatment. The OS results shown with the belantamab mafodotin combination in DREAMM-7 further cement the potential of this regimen to prolong the lives of patients with relapsed or refractory multiple myeloma compared to a standard of care daratumumab combination."

The belantamab mafodotin combination also showed statistically significant superiority on the key secondary endpoint of minimal residual disease (MRD) negativity (no detectable cancer cells) compared to the daratumumab combination. The greater than 2.5-fold improvement in the rate of MRD negativity seen at the time of the primary analysis for patients who received BVd can now be declared as statistically significant ($p<0.00001$) after the positive OS readout based on the predefined testing procedure. This further underscores the transformative potential of this belantamab mafodotin combination for multiple myeloma patients at or after their first relapse.

In addition to OS and MRD negativity, the belantamab mafodotin combination resulted in clinically meaningful improvements in all key secondary efficacy endpoints compared to the daratumumab combination, including duration of response (DOR) and progression-free survival 2 (PFS 2). The results indicate deeper and more durable responses among patients treated with BVd compared to DVd.

The safety and tolerability of the belantamab mafodotin regimen were consistent with the primary analysis and known safety profile of the individual agents. Grade 3 or higher adverse events of clinical interest in the belantamab mafodotin combination and daratumumab combination arms, respectively included thrombocytopenia (56% versus 35%; 34 versus 25 patients/100 person-years); anemia (9% versus 10%; exposure-adjusted rate [per 100 person-years] not reported); and neutropenia (14% versus 10%; 8 versus 7 patients/100 person-years).

Eye-related side effects, a known risk of treatment with belantamab mafodotin, were generally manageable and resolvable with dose modification, and led to a low (10%) treatment discontinuation rate.

Full data summaries for OS and other key secondary endpoints are shown below.

Key Secondary Endpoints		
Endpoint	**belantamab mafodotin + bortezomib + dexamethasone (BVd)** n=243	**daratumumab + bortezomib + dexamethasone (DVd)** n=251
OS (overall survival), HR (95% CI)	0.58 (0.43-0.79)	
P-value[1]	p=0.00023	
OS, median (95% CI), months	NR (NR-NR)	NR (41.0-NR)
OS rate at 24 months, % (95% CI)	79% (73-84)	67% (61-73)
OS rate at 36 months, % (95% CI)	74% (68-79)	60% (54-66)
MRD (minimal residual disease) negativity rate for patients with CR or better, % (95% CI)	25.1% (19.8-31.0)	10.4% (6.9-14.8)
ORR (overall response rate), % (95% CI)	83.1% (77.8-87.6)	71.3% (65.3-76.8)
CR (complete response), or better, % (95% CI)	35.8% (29.8-42.2)	17.5% (13.0-22.8)
VGPR (very good partial response), or better, % (95% CI)	66.3% (59.9-72.2)	46.2% (39.9-52.6)
Median DOR (duration of response) (95% CI), months	40.8 (30.5-NR)	17.8 (13.8-23.6)
Median PFS 2 (progression-free survival 2), months	NR (45.6-NR)	33.4 (26.7-44.9)
HR	0.59 (0.45-0.77)	

[1]One-sided p-value based on stratified log-rank test.

In 2024, regulatory filings for belantamab mafodotin combinations for the treatment of relapsed or refractory multiple myeloma based on the results of the DREAMM-7 and DREAMM-8 trials have been accepted in the US[4], European Union[5], Japan[6] (with priority review), China (for DREAMM-7 only, with priority review; Breakthrough Therapy Designation[7] also granted), United Kingdom, Canada and Switzerland (with priority review for DREAMM-8).

About the DREAMM clinical development program
The DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical development program continues to evaluate the potential of belantamab mafodotin in early lines of treatment and in combination with novel therapies and standard of care treatments. In addition to DREAMM-7 and DREAMM-8, a phase III study in newly diagnosed transplant ineligible multiple myeloma, DREAMM-10, is expected to be initiated by the end of 2024.

About DREAMM-7
The DREAMM-7 phase III clinical trial is a multi-center, open-label, randomized trial evaluating the efficacy and safety of belantamab mafodotin in combination with bortezomib plus dexamethasone (BVd) compared to a combination of daratumumab and bortezomib plus dexamethasone (DVd) 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 randomized at a 1:1 ratio to receive either BVd or DVd. 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[1] 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 multiple myeloma
Multiple myeloma is the third most common blood cancer globally and is generally considered treatable but not curable.[8,9] There are approximately more than 180,000 new cases of multiple myeloma diagnosed globally each year.[10] Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.[11] Many patients with multiple myeloma, including approximately 65% in the US, 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 center.[12,13,14]

About belantamab mafodotin
Belantamab mafodotin is an investigational antibody-drug conjugate comprising a humanized 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.

GSK in oncology
Oncology is an emerging therapeutic area for GSK where we are committed to maximizing patient survival with a current focus on hematologic malignancies, gynecologic cancers and other solid tumors through breakthroughs in immuno-oncology and tumor-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 us.gsk.com.

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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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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[1] 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/.
[2] GSK press release issued 02 June 2024. Blenrep combination reduced the risk of disease progression or death by nearly 50% versus standard of care combination in relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-combination-reduced-the-risk-of-disease-progression/.
[3] Post hoc analysis using simulation to predict median OS values in each arm utilising the observed data at the interim analysis with 39.4-month median follow up to extrapolate time to death of ongoing censored patients. Predicted median OS values subject to change as data matures.
[4] GSK press release issued 25 November 2024. Blenrep combinations accepted for review by the US FDA for the treatment of relapsed/refractory multiple myeloma. Available at: https://www.gsk.com/en-gb/media/press-releases/blenrep-combinations-accepted-for-review-by-the-us-fda-for-the-treatment-of-relapsedrefractory-multiple-myeloma/.
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