Pivotal DREAMM-2 Study: Single-agent Belantamab Mafodotin (GSK2857916) in Patients With Relapsed/Refractory Multiple Myeloma (RRMM) Refractory to Proteasome Inhibitors (PIs), Immunomodulatory Agents, and Refractory and/or Intolerant to Anti-CD38 Monoclonal Antibodies (mAbs)

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Background
Belantamab mafodotin (GSK2857916) is a novel, single-agent Immunoreceptor Tyrosine-Associated Protein (ITAM)-based mAb targeting BCMA, which is highly expressed in myeloma cells. The primary endpoints in this phase 2 study of relapsed/refractory myeloma patients were objective response rate (ORR) and confirmed partial response (cPR) lasting ≥8 weeks without disease progression or death, associated with improved overall survival (OS). Here, we report updated ORR and cPR rates and updated OS from the phase 2 trial of 3 mg/kg and 2.5 mg/kg of belantamab mafodotin.

Methods
DREAMM is an open-label, single-arm, multicenter, phase II study of relapsed/refractory myeloma patients treated with belantamab mafodotin 3 mg/kg or 2.5 mg/kg. OS was the primary endpoint. This analysis was conducted after an independent data safety monitoring board recommended that the trial continue to enroll and analyze in the 3 mg/kg arm. Medications were given intravenously over 2 hours every 3 weeks. Patients were stratified into 2 cohorts based on prior anti-CD38 mAb treatment (yes vs no). The median age was 64 years (range, 30–94 years). A total of 113 patients were enrolled. Patients treated with 3 mg/kg had a median follow-up of 7 months, and patients treated with 2.5 mg/kg had a median follow-up of 12 months.

Results

1. **ORR and cPR:**
   - **3 mg/kg:** ORR was 33.3% (95% CI, 18.7–49.2%) and cPR was 12.2% (95% CI, 5.1–22.5%).
   - **2.5 mg/kg:** ORR was 23.5% (95% CI, 12.2–39.8%) and cPR was 9.4% (95% CI, 3.3–16.2%).

2. **OS:**
   - Median OS was 13.8 months (95% CI, 10.0–17.1) in the 3 mg/kg group and 13.8 months (95% CI, 10.0–17.1) in the 2.5 mg/kg group.

3. **Safety:**
   - Adverse events (AEs) were consistent with the known safety profile of belantamab mafodotin. The most frequent AEs with any grade were neutropenia, neutrophil count decreased, and fatigue. The most frequent AEs of grade 3 or 4 were neutropenia, neutrophil count decreased, and fatigue.

Discussion and Conclusions
Single-agent belantamab mafodotin offers a novel treatment option for patients with relapsed/refractory RRMM who are intolerant to other treatments. This study provides additional evidence of the safety and efficacy of belantamab mafodotin and supports the further development of belantamab mafodotin for patients with RRMM.

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**References**

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