**Background**

BCMA and belantamab mafodotin

BCMA is a cell-surface receptor, expressed on MM cells but absent in naive and memory B cells, that promotes plasma cell survival.1 Belantamab mafodotin (belamaf, GS-2829716) is a first-in-class BCMA-targeting, humanized, afucosylated, monoclonal antibody-drug conjugate with multivalency activity involving immune-independent ADC-mediated apoptosis as well as immune-dependent mechanisms such as ICOD and ADDOC/DAPC.2

In the pivotal Phase II DREAMM-2 study (NCT03525678), single-agent belamaf demonstrated durable and deep responses, was well tolerated, and had an acceptable safety profile in patients with heavily pre-treated RM/MM.3

**Methods**

**DREAMM-9 (NCT04091126) is a:**

3 Phase II Open-label Randomized Multicenter study

**Patients in Part 1 are:**
- not allowed to switch to Part 2
- not allowed to alter their allocated dose
- permitted reduced dose

Patients will receive study treatment until disease progression or unacceptable toxicity occurs.

**Key assessments:**
- Primary dual endpoints, PFS and MRD negativity rates, will be assessed.
- Safety/efficacy and various AEIs will be assessed throughout the study.

**Key inclusion criteria**
- Age ≥ 18 years
- Confirmatory diagnosis of MM (WHO criteria)
- Ineligible for high-dose chemotherapy with ASCIT
- Active organ dysfunction

**Key exclusion criteria**
- Smoldering MM
- Prior systemic chemotherapy or investigational drug ≥ 14 days prior to first dose of belamaf
- Periphere neuropathy or neuropathic pain (Grade 2 or higher, NCI-CTCAE 4.0)
- Major surgery < 4 weeks prior to first dose of belamaf
- Active infection or bleeding from any source
- Previous/current malignancies other than MM, unless considered medically stable for ≥ 2 years
- Certain co-morbid conditions,除外 mild pulmonary hypertension
- Light chain disease, prior PD1/PD-L1 blockade
- Prior autologous stem cell transplant

**Summary**

The DREAMM-9 study was designed to determine the efficacy and safety of combining single-agent belamaf with VRd versus VRd alone in patients with NDMM.

**Study Endpoints**

**Part 1:**

1. **Dose escalation and cohort expansion**
2. **Phase II:**
   - **Primary endpoints**
     - ORR (≥PR)
     - CRR (CR or sCR)
   - **Exploratory endpoints**
     - Median DoR
     - MRD-negativity rate (10⁻⁴, –⁹ sensitivity by NGS)
     - Time to progression (TTP)
     - Time to best response (TTBR)

**Part 2:**

1. **Randomized Phase II**
2. **Induction Treatment**
   - Belamaf selected dose + VRd
3. **Maintenance Treatment**
   - Belamaf selected dose + Rd

**Summary**

Belamaf represents a new treatment option for patients with RRMM.

**Screening for the DREAMM-9 study began in 2019, and the study is currently recruiting.**

**Single-agent belamaf is being evaluated in other clinical trials in various combination strategies (oral presentation no. 650 and poster no. 442), in addition to evaluation as monotherapy (poster nos. 439, 441 and 441) in various MM settings.**

**Acknowledgments**

All named named authors have consented to the submission of this abstract. All authors have contributed to the research, preparation, and submission of this abstract.

**Disclosures**

All named authors, or their immediate family members, have no financial relationships with or conflicts of interest to report. All authors have nothing to disclose.

**References**


**Ethics approval statement**

The belamaf single-agent study (NCT04091126) has been approved by the ethics committee of each participating institution. The dose-escalation study (NCT04094705) has been approved by the ethics committee of each participating institution. The combination study (NCT04091126) has been approved by the ethics committee of each participating institution.

**Presented at the American Society for Clinical Oncology (ASCO) Congress, Virtual Scientific Program, May 29–31, 2020**

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