TPS7567 Poster Session

Design of the phase 3 DREAMM-10 study: Belantamab mafodotin plus lenalidomide and dexamethasone (BRd) vs daratumumab plus lenalidomide and dexamethasone (DRd) in transplant-ineligible, newly diagnosed multiple myeloma (TI-NDMM).

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Background: Treatment options have advanced for patients (pts) with TI-NDMM, but outcomes remain worse compared to pts with transplant-eligible NDMM, indicating a need for novel therapies to improve the prognosis of TI-NDMM. Belantamab mafodotin is an antibody-drug conjugate targeting B-cell maturation antigen. Phase 3 studies have shown significant survival benefits with belantamab mafodotin in combination regimens vs standard of care combinations for relapsed/refractory MM [1–3], and preliminary data have shown promising clinical activity with belantamab mafodotin combination regimens, including BRd, for TI-NDMM [4,5]. The design of the DREAMM-10 study, investigating BRd vs DRd in pts with TI-NDMM, is presented here. **Methods:** DREAMM-10 (NCT06679101) is a randomized, phase 3, open-label, multicenter study. Pts aged ≥18 years with TI-NDMM, measurable disease, and Eastern Cooperative Oncology Group performance status 0–2 are eligible. Specific reasons for transplant ineligibility will be collected. Pts who were previously treated for MM or smoldering MM are excluded. Approximately 520 eligible pts will be randomized 1:1 to BRd or DRd, stratified by age (<75, ≥75 years), International Staging System (I, II, III), and region (North America, rest of world). Belantamab mafodotin will be administered intravenously at 1.9 mg/kg every 8 weeks for 24 weeks, then 1.9 mg/kg every 12 weeks thereafter. Daratumumab will be administered subcutaneously using the approved dose and schedule. In both treatment arms, lenalidomide will be administered orally at 25 mg on Days 1–21, and dexamethasone will be administered orally at 40 mg on Days 1, 8, 15, and 22 of every 28-day cycle. Pts will be treated until disease progression, death, unacceptable toxicity, consent withdrawal, or end of study. The dual primary endpoints are progression-free survival (PFS) and minimal residual disease negativity rate. Key secondary endpoints are overall survival and PFS2 (time from randomization to progression on first subsequent anti-myeloma therapy or death). The statistical plan includes multiplicity adjustment for primary endpoints and hierarchical testing for key secondary endpoints. Other efficacy endpoints, safety (adverse events [AEs]/serious AEs), and health-related quality of life will also be assessed. The study opened for enrollment on December 30, 2024. 1. Hungria V, et al. *N Engl J Med* 2024. 2. Dimopoulos MA, et al. *N Engl J Med* 2024. 3. https://us.gsk.com/media/11819/belamaf-dreamm-7-os-full-data-press-release_final_us-version-08dec24.pdf. 4. Terpos E, et al. *Haematologica* 2024. 5. Usmani SZ, et al. *Blood* 2024;144(Suppl 1):497. Clinical trial information: NCT06679101. Research Sponsor: GSK (214828); drug linker technology licensed from Seagen; monoclonal antibody produced using POTELLIGENT Technology licensed from BioWa.