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653.MULTIPLE MYELOMA: PROSPECTIVE THERAPEUTIC TRIALS

Safety of Elranatamab in Patients with Triple-Class Refractory Relapsed/Refractory Multiple Myeloma (RRMM) in Magnetismm-17, a North American Expanded Access Protocol

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BACKGROUND
In the phase 2, registrational MagnetisMM-3 (NCT04649359) trial, patients with RRMM who had not previously received a B cell maturation antigen (BCMA)-directed therapy (n=123) achieved an objective response rate of 61% with single-agent elranatamab (ELRA), a BCMA-CD3 bispecific antibody. Common treatment-emergent adverse events (TEAEs) included infections (70%; 40% grade [G] 3/4) and CRS (58%; all G1/2). Here we report on the safety of ELRA in the MagnetisMM-17 (MM-17; NCT05462639) trial, a North American Expanded Access Protocol (EAP).
METHODS
MM-17 is an ongoing, single-arm, open-label study for patients with triple-class refractory RRMM (refractory to ≥1 proteasome inhibitor, ≥1 immunomodulatory drug, and ≥1 anti-CD38 antibody), and who had no prior BCMA-directed therapy. Patients must be ≥18 years of age and have a confirmed diagnosis of MM, measurable disease by IMWG criteria, an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0-1, adequate organ function, and no active, uncontrolled infection. The study is being conducted in the US and Canada. The primary objective is to provide access to ELRA for patients with RRMM and no access to comparable/alternative therapy. The secondary objective is to evaluate the safety and tolerability of ELRA.
Patients received subcutaneous ELRA 76 mg once every week on a 28-day cycle after step-up doses of 12 and 32 mg during week 1. Dose frequency was reduced to once every 2 weeks (Q2W) after ≥6 cycles in patients with persistent response (≥partial response), and then from Q2W to Q4W after ≥6 Q2W cycles. Patients received ELRA until disease progression, unacceptable toxicity, withdrawal of consent, study termination, or ELRA becomes commercially available. TEAEs were graded by NCI CTCAE v5.0, except cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) which were graded according to the American Society for Transplantation and Cellular Therapy criteria (ASTCT).
RESULTS
As of April 28, 2023, 20 patients had enrolled in the trial. Median patient age was 72.5 years (range 53-82); 50% male, 85% white, and 15% Black/African American. At baseline, most patients had an ECOG PS of 1 (95%), and 40% had R-ISS disease stage III. Patients had a median of 4 prior lines of therapy (range 2-8); 95% and 35% of patients had triple-class and penta-drug refractory disease, respectively. At the time of data cut-off, 2 patients had discontinued due to progressive disease. Median treatment duration was 0.95 months (range 0.26-2.83); median relative dose intensity was 98.3% (range 48-105).
TEAEs were reported in all 20 patients, with G3 or G4 events reported in 13 (65%). There were no G5 events.

Thirteen (65%) patients developed CRS, all events were G1 (50%) or G2 (15%); no events G ≥3 were reported. After the first step-up dose, 11 (55%) patients had a CRS event. CRS events occurred in 3 patients (15%) and 1 patient (5%) after the second step-up dose and first treatment dose, respectively. The median time to onset was 2 days (range 1-4), and the median time to resolution was 3 days (range 1-5).
ICANS occurred in 2 of the 20 patients (10%), both events were G1, with 1 occurring after the first step-up dose and the other after the second step-up dose. The median time to onset was 3 days (range 3-3) and the median time to resolution was 2.5 days (range 2-3).
Four (20%) patients had infections, including 1 event each of G1 sinusitis, G2 acute sinusitis, G2 folliculitis, G2 upper respiratory tract infection and G3 bacterial conjunctivitis. Cytopenias were reported in 11 (55%) patients. The most common (occurring in ≥3 [15%] patients) cytopenias were neutropenia (30%; G3/4 25%), lymphopenia (20%; G3/4 15%), and thrombocytopenia (15%; G3/4 10%).
CONCLUSIONS
Early safety data (median treatment duration <1 month) from this ongoing expanded access protocol of elranatamab in patients with RRMM are consistent with results from the phase 2, registrational MagnetisMM-3 trial, with no new safety signal identified.

Disclosures Bahlis: *Takeda:* Consultancy; *Forus:* Consultancy, Honoraria; *GSK:* Consultancy, Other: member of steering committee; *BMS:* Consultancy, Honoraria; *Celgene:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Abbvie:* Consultancy, Honoraria, Other: member of steering committee; *Karyopharm therapeutics:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Genentech/Roche:* Honoraria; *Amgen:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Sanofi:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Pfizer:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Janssen:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: IRC member and chair, Research Funding. **Trudel:** *BMS:* Consultancy, Honoraria, Research Funding; *K36:* Consultancy; *FORUS:* Consultancy; *Pfizer:* Honoraria, Research Funding; *Genentech:* Research Funding; *GSK:* Consultancy, Honoraria, Research Funding; *Roche:* Consultancy, Research Funding; *Janssen:* Honoraria, Research Funding; *Amgen:* Honoraria, Research Funding; *Sanofi:* Honoraria. **Maisel:** *Verastem:* Honoraria; *Takeda:* Honoraria; *Kite:* Honoraria; *Karyopharm:* Honoraria; *Janssen:* Honoraria; *Incyte:* Honoraria; *Celgene:* Honoraria; *Amgen:* Honoraria; *Bayer:* Consultancy. **Monge:** *Janssen:* Consultancy. **Larson:** *1200 Pharma:* Current equity holder in private company; *Ionis:* Research Funding; *AbbVie:* Research Funding; *Novartis:* Research Funding; *Allogene:* Research Funding; *TORL Biotherapeutics:* Current equity holder in private company; *Janssen:* Research Funding; *ImmPACT Bio:* Research Funding; *Pfizer:* Research Funding; *Bristol Myers Squibb:* Research Funding; *Bioline:* Research Funding. **Dong Ma:** *Pfizer, Inc.:* Current Employment. **De Nicolo:** *Pfizer, Inc.:* Current Employment. **Perez-Cruz:** *Pfizer:* Current Employment.

OffLabel Disclosure: Elranatamab is an investigational BCMA-CD3 bispecific antibody for the treatment of patients with multiple myeloma.

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