

3. RELAPSED/REFRACTORY MULTIPLE MYELOMA

ANALYSIS OF PATIENTS WITH PRIOR BCMA-TARGETED THERAPY AND THOSE ACHIEVING COMPLETE RESPONSE IN REALiTAL: A MULTI-COUNTRY OBSERVATIONAL STUDY OF TALQUETAMAB IN RELAPSED/REFRACTORY MULTIPLE MYELOMA OUTSIDE OF CLINICAL TRIALS

R. Popat¹, K. M. Kortüm², H. Magen³, V. Mykytiv⁴, C. Liberatore⁵, E. Zamagni⁶, M.C. Da Vià⁷, E. Antonioli⁸, M. Hansson⁹, D. Santra¹⁰, D. Greer¹¹, K. Subrt¹², P. Hu¹³, E. Aeby¹⁴, N. Francella¹⁵, N.M. Suñe¹⁶, A. Perrot¹⁷, K. Uttervall¹⁸

¹University College London Hospitals NHS Foundation Trust, UK; ²University Hospital of Würzburg, Germany; ³Tel Aviv University, Israel; ⁴Cork University Hospital, Ireland; ⁵Ospedale Santo Spirito, Pescara, Italy; ⁶University of Bologna, Italy; ⁷IRCCS Fondazione Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy; ⁸Careggi Hospital and University of Florence, Italy; ⁹Sahlgrenska University Hospital, Gothenburg, Sweden; ¹⁰¹¹Parexel International; ¹²¹³¹⁴¹⁵¹⁶Johnson & Johnson; ¹⁷Université de Toulouse, France; ¹⁸Karolinska University Hospital, Stockholm, Sweden

Introduction. Talquetamab is the first approved bispecific antibody targeting GPRC5D and CD3 for patients with triple-class-exposed RRMM. In MonumentAL-1 (N=375), talquetamab elicited deep, durable responses that persist with long-term follow-up (median 38.2 months [QW], 30.3 months [Q2W], and 30.3 months [prior T-cell redirecting therapy (TCRT)]). Here, we report outcomes in patients receiving prior anti-BCMA TCRT and patients achieving complete response (CR) in REALiTAL.

Methods. REALiTAL is a retrospective, international, non-interventional study that aims to describe the management and clinical outcomes of patients receiving talquetamab outside of clinical trials. Eligible patients provided informed consent and received the first dose of talquetamab on or before December 31, 2023. Data, including baseline characteristics, prior therapies, effectiveness, and safety information, were collected from medical records. Overall response rates (ORRs), time to first response (TTFR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS) were assessed.

Results. Overall, 93 eligible patients (82 starting Q2W dosing) were included across 26 sites in 7 countries. Patients received a median of 5 prior lines of therapy. With a median follow-up of 15 (0.4–25.3) months, ORR was 66.7% (95% CI, 56.1–76.1), with 57% of patients achieving a very good partial response or better (\geq VGPR). Median DOR, PFS, and OS were 12.3 months (95% CI, 7.9–not estimable; NE), 8.2 months (95% CI, 6.1–10.7), and 25.3 months (95% CI,

17.3–NE), respectively. In those achieving CR (n=17 [18.3%]), median DOR, PFS, and OS were NE (95% CI, 8.84–NE), NE (10.71–NE), and NE (NE–NE), respectively. Among patients with prior anti-BCMA TCRT (n=33 [35.5%]), 12 received prior CAR-T and 23 received prior bispecific antibody (BsAb) therapy. For prior CAR-T and prior BsAb groups, ORRs were 66.7% (95% CI, 34.9–90.1) and 56.5% (95% CI, 34.5–76.8), with a median TTFR of 1.6 and 1 month after a median duration of talquetamab treatment of 11.7 and 6.3 months, respectively. For the prior CAR T group, median DOR was NE (95% CI, 1.45–NE), PFS was 10.7 months (95% CI, 2.23–NE), and OS was NE (95% CI, 4.47–NE). In the prior BsAb group, median DOR, PFS, and OS were 16.1 months (95% CI, 5.95–NE), 7.4 months (95% CI, 3.88–18.20), and NE (95% CI, 9.20–NE). Treatment-emergent adverse events occurred in 98.9% of patients and were mostly grade 1/2. Cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome occurred in 55.9% (grade 3, 1.1%) and 2.2% (0 grade 3) of patients, respectively. Skin/nail and oral toxicities occurred in 67.7% (grade 3/4, 1.1%) and 66.7% (grade 3/4, 1.1%) of patients, respectively. Dysgeusia occurred in 56.9% of patients.

Conclusions. REALiTAL showed similar efficacy and a manageable safety profile to that observed in MonumentAL-1. Talquetamab demonstrated durable responses, especially in patients achieving CR, including those who had prior anti-BCMA TCRT, highlighting talquetamab's potential as an effective real-world treatment for RRMM. □