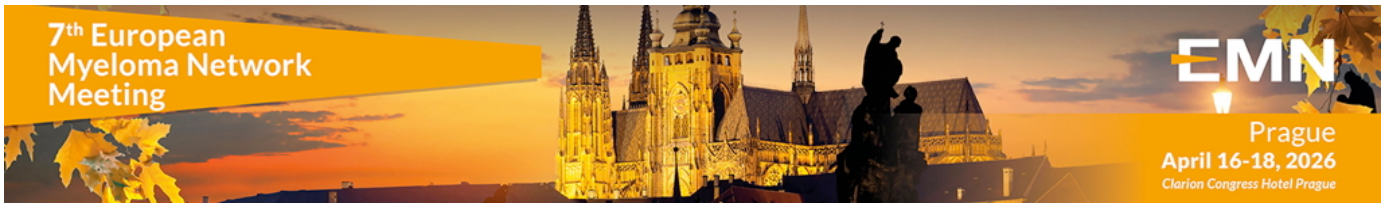




3. RELAPSED/REFRACTORY MULTIPLE MYELOMA

# FIRST RESULTS OF REALITEC-2: SECOND COHORT OF REALITEC, AN INTERNATIONAL OBSERVATIONAL RETROSPECTIVE STUDY OF TECLISTAMAB IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA IN ROUTINE CLINICAL PRACTICE

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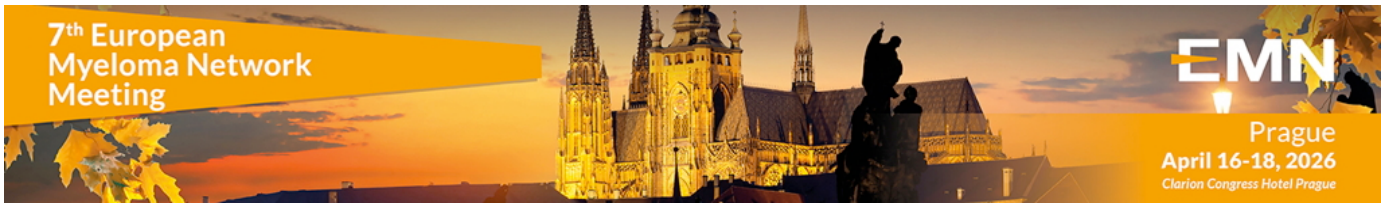
**Background.** Teclistamab is the first approved bispecific antibody targeting BCMA and CD3 for the treatment of triple class exposed relapsed/refractory multiple myeloma (RRMM). REALiTEC is a multicohort retrospective observational study evaluating the use of teclistamab in routine clinical practice. The first cohort comprised predominantly of patients treated in pre-approval access programs (85%). With a median follow up of 20.7 months, overall response rate (ORR) was 60.2%, with most responses (52.2%) being very good partial response or better (≥VGPR). Median duration of response (DOR), progression free survival (PFS), and overall survival (OS) were consistent with those reported in MajesTEC-1, despite inclusion of a heavily pretreated, difficult to treat patient population. Here, we present for the first time the results from REALiTEC cohort 2, which included patients treated with commercial teclistamab in Europe and Israel.

**Methods.** REALiTEC is a non-interventional study that aims to describe the outcomes of patients treated with teclistamab in routine clinical practice. Data were collected from patients' medical records, including demographics, disease characteristics, prior therapies, effectiveness and safety.

**Results.** A total of 260 patients who received the first dose of teclistamab from 01 January 2024 to 31 December 2024 were included in the study. The median age was 68 years (range 40–100), with 27.3% of patients aged ≥75 years. High risk cytogenetics were present in 36.2% of patients, 11.2% had documented true extramedullary disease, and 60% would not have met the eligibility criteria for MajesTEC-1. Median number of prior lines of therapy (pLOT) was 4 (2-14) with 31.5% of patients having 3 or less pLOT; 15.8% of patients were previously exposed to BCMA targeted agents; 43.8% were refractory to their last line of therapy, and 24.6% were triple and 7.3% penta drug refractory. With a median follow up of 12.7 months (95% CI, 11.8–13.7), the median treatment duration was 10.8 months (95% CI, 7.92–13.2). ORR was 66.5% (95% CI, 60.4–72.2%), with ≥VGPR attained in 54.6% (95% CI, 48.3–60.8%) of patients. Median time to first response was 1.8 months (95% CI, 1.5–2.1) and median time to best response was 3.6 months (95% CI, 2.8–4.2). Median DOR was not reached (NR; 13.54, NE), with a 12-month DOR estimate of 64.4% (95% CI, 54.3–72.8%). Median PFS was 15.2 months (95% CI, 10.8–NE) and median OS was NR (20.53, NE), with a 12-month OS estimate of 69.8% (95% CI, 63.4–75.3%). Patients achieving deep responses (≥VGPR) had significantly longer DOR, PFS and OS (p‹0.001). Most common adverse events were infections (any grade 61.9%; grade 3–4: 26.5%), cytokine release syndrome (any grade 55%; grade 3–4: 1.2%), and cytopenias: anaemia (any grade 30%; grade 3–4: 18.1%), neutropenia (any grade 27.3%; grade 3–4: 23.8%), and thrombocytopenia (any grade 16.9%; grade 3–4: 15%). At least one dose of immunoglobulin G (IgG) replacement therapy was administered to 73.5% of patients. Treatment discontinuation due to AEs occurred in 10% of patients. Seventy-three patients received subsequent therapies, including 24 who received a GPRC5D-targeted bispecific antibody.

**Conclusions.** The REALiTEC-2 study shows improved outcomes as compared to the REALiTEC first cohort, in line with a more contemporary clinical practice, with teclistamab being used earlier in the disease, what translated in-






to improved long-term effectiveness and safety outcomes.