

Trial in Progress: REALiTEC-2, an International Retrospective Study of Clinical Outcomes in Patients With Relapsed Refractory Multiple Myeloma Treated With Teclistamab in the Real World

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Key Takeaway



REALiTEC-2 enrolled 300 patients treated between January 1, 2023, and December 31, 2024; publication of first results is planned for the first quarter of 2026

Conclusions



More than 15,900 patients have been treated to date with commercial teclistamab in routine clinical practice worldwide



The first REALiTEC cohort provided highly informative data from patients treated in pre-approval access programs. REALiTEC-2 aims to provide up-to-date data in a more contemporary patient population treated with commercial teclistamab



REALiTEC-2 is a retrospective, non-interventional, multi-country study aiming to provide valuable data from patients treated in the real world, complementing the initial REALiTEC study, to add to our understanding of the evolving use of teclistamab in a broader patient population in Europe and Israel (NCT06285318)



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Background

- Teclistamab is the first approved T-cell redirecting bispecific monoclonal antibody for the treatment of triple-class exposed patients with relapsed/refractory multiple myeloma (RRMM)¹⁻⁴
- Teclistamab approval was based on data from the MajesTEC-1 study showing a high overall response rate (ORR) at the recommended phase 2 dose of teclistamab in patients with triple-class exposed RRMM¹⁻⁴
 - ORR was 63.0%; complete response or better (\geq CR) was 46.1% and very good partial response or better (\geq VGPR) was 59.4%⁴
 - Median duration of response (DOR) was 24.0 months, median progression-free survival (PFS) was 11.4 months, and median overall survival (OS) was 22.2 months⁴

- Clinical trials are not always representative of all the patients being treated routinely due to regulatory-required eligibility criteria⁵
- Non-trial populations represent a considerable proportion of patients seen in clinics and may have different baseline/disease characteristics compared with clinical trial cohorts; however, information on the management and outcomes of these patients is limited
- There is therefore a growing need for supplementary evidence generated outside of the clinical trial setting to further support the safety and efficacy of emerging antimyeloma treatments
- The REALiTEC-2 study aims to provide valuable data on the use of teclistamab in patients treated in the real world

- The first cohort of REALiTEC⁶, primarily comprising heavily pre-treated patients from pre-approval access programs with a median 6 prior lines of therapy, reported similar outcomes to MajesTEC-1
 - ORR for all patients was 60.2%, with most (52.2%) being \geq VGPR
 - Median DOR, PFS, and OS were 20.3 months, 9.7 months, and 26.3 months, respectively
 - Patients achieving deep responses (\geq VGPR) had a longer DoR (median 26.1 months), with 12-month PFS and OS rates of 71.2% and 83.1%, respectively.
 - The safety profile was consistent with MajesTEC-1, with no new safety signals observed
- REALiTEC-2 will include patients treated with commercial teclistamab across a wider range of countries

Methods

Study design and patients

- REALiTEC-2 is a retrospective, non-interventional, international study to describe the use of teclistamab in RRMM patients treated in routine clinical practice with commercial teclistamab
- Data available from the medical records of each participant will be collected to assess baseline demographics and disease characteristics, treatment history, treatment patterns, response, safety, and subsequent therapies (**Figure 1**)
- If feasible, exploratory subgroup analysis will be performed in selected patient populations (i.e., renal impairment, elderly, prior BCMA)

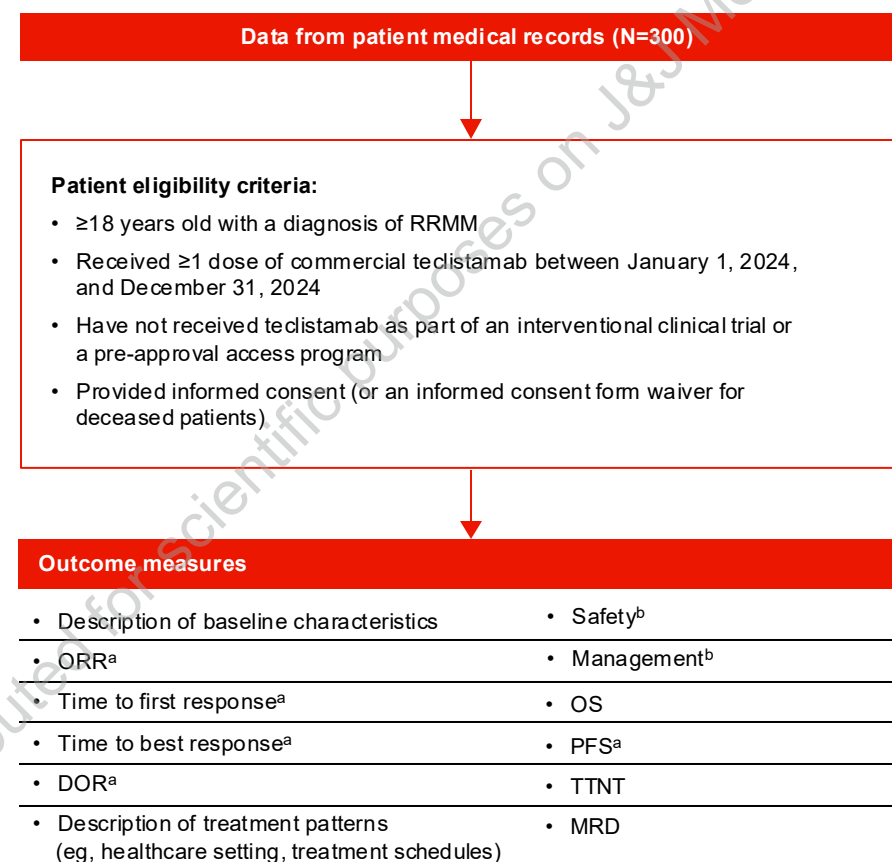
Patient enrollment

- To reflect the different practices and management strategies between countries, 63 sites from 10 countries in Europe (Denmark, France, Germany, Greece, Ireland, Italy, Norway, Spain, Sweden, and the UK) and Israel were approached
- Enrollment began in April 2025 and is currently ongoing
- Eligible patients had to receive their first dose of teclistamab within the period of January 1, 2023, to December 31, 2024, inclusive, to ensure sufficient data availability at the time of enrollment

Statistical analysis

- There is no formal statistical hypothesis, and the study objectives are descriptive
- The sample size was based on feasibility
- Database lock is scheduled for November 2025

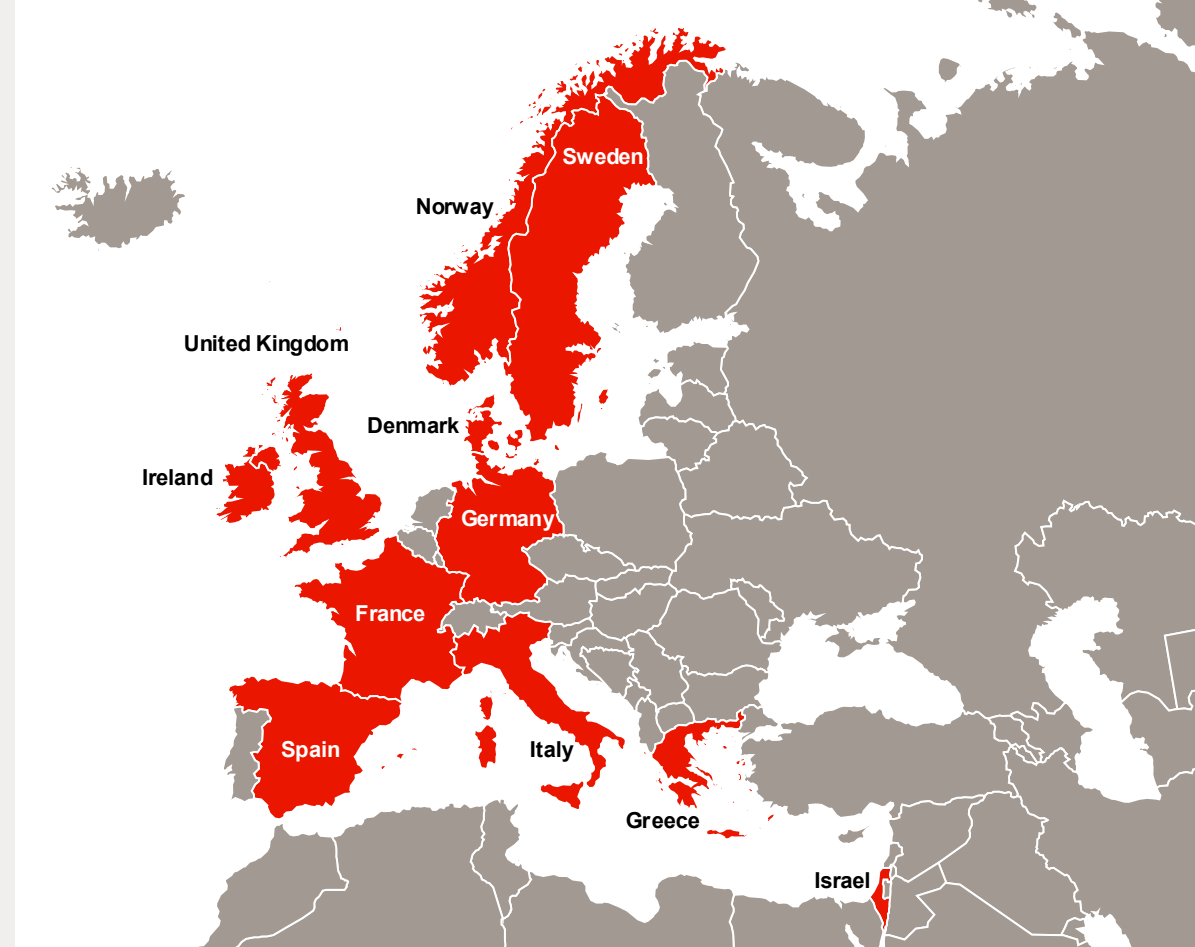
Figure 1: REALiTEC-2 study design



Study conduct will be monitored externally, and eligibility reviewed centrally.

^aAs assessed by the investigator per International Myeloma Working Group response criteria. ^bIncidence and severity of AEs, including immune effector cell-associated neurotoxicity syndrome, cytokine release syndrome and other AEs, as well as medications used for prophylaxis and management of AEs will be reported. AE, adverse event; MRD, minimal residual disease; TTNT, time to next treatment.

Figure 2: Countries participating in REALiTEC-2



References

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Multiple Myeloma

