P-064

Trial in Progress (REALiTEC): A Retrospective Multi-Country Study of Clinical Outcomes in Patients With Relapsed/Refractory Multiple Myeloma Treated With Teclistamab Outside of Clinical Trials

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Current status

REALiTEC enrolled 113 patients between December 2023 and August 2024

Overview

REALiTEC is a retrospective, non-interventional, multi-country study aiming to describe the use of teclistamab in patients with RRMM outside of clinical trials

The REALiTEC study aims to provide valuable data on the use of teclistamab in patients treated in early access programs and routine clinical care

ClinicalTrials.gov

NCT06285318

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Disclosures

AP has received honoraria or consultancy payments from AbbVie, Amgen, BMS, Janssen, Pfizer, Sanofi, and Takeda.

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 RRMM[1-4]
  - ORR was 63.0%; complete response or better was 46.1%[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 months[4]
- A recent analysis of the Connect MM Registry reported that up to 40% of patients treated in routine clinical practice would be ineligible for enrollment in randomized clinical trials, such as MajesTEC-1, due to regulatory required eligibility criteria[5]
- Non-trial populations represent a considerable proportion of patients seen in clinics and may have substantially 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 from studies outside of the clinical trial setting to further support the safety and efficacy of emerging antimyeloma treatments
- Such studies are useful in addressing evidence gaps, providing data on populations often underrepresented in clinical trials and informing adverse event (AE) management and therapy sequencing
- The REALiTEC study – with the current and future planned cohorts – aims to provide valuable data on the use of teclistamab in patients treated in early access programs and early commercial phases
- Future recruitment of 2 additional cohorts into the REALiTEC study is planned to expand the data collected from real-world clinical experience with teclistamab and to capture the evolution of practices for patient management across Europe

Methods

Study design and patients

- REALiTEC is a retrospective, non-interventional, multi-country study aiming to describe the safety and efficacy of teclistamab in patients with RRMM outside of clinical trials (**Figure 1**)
- Data available from the medical records of each enrolled participant will be collected to assess baseline demographics and disease characteristics, treatment history, treatment patterns, response, safety, and subsequent therapies (**Figure 1**)
- Exploratory subgroup analyses may be performed in selected patient populations, such as those with severe hepatic or renal impairment or extramedullary disease, if sufficient patients from these subgroups are enrolled
- Study outcome measures will be assessed from the first dose of teclistamab up to the date of informed consent

Patient enrollment

- 113 patients have been enrolled from 23 sites across 8 countries (Germany, UK, France, Denmark, Italy, Spain, Sweden, and Israel; **Figure 2**)

Statistical analysis

- There is no formal statistical hypothesis, and the study objectives are descriptive
- The sample size was based on feasibility
- Final analysis is scheduled for November 2024

Figure 1: REALiTEC study design

Data from patient medical records (N=113)

Patient eligibility criteria:

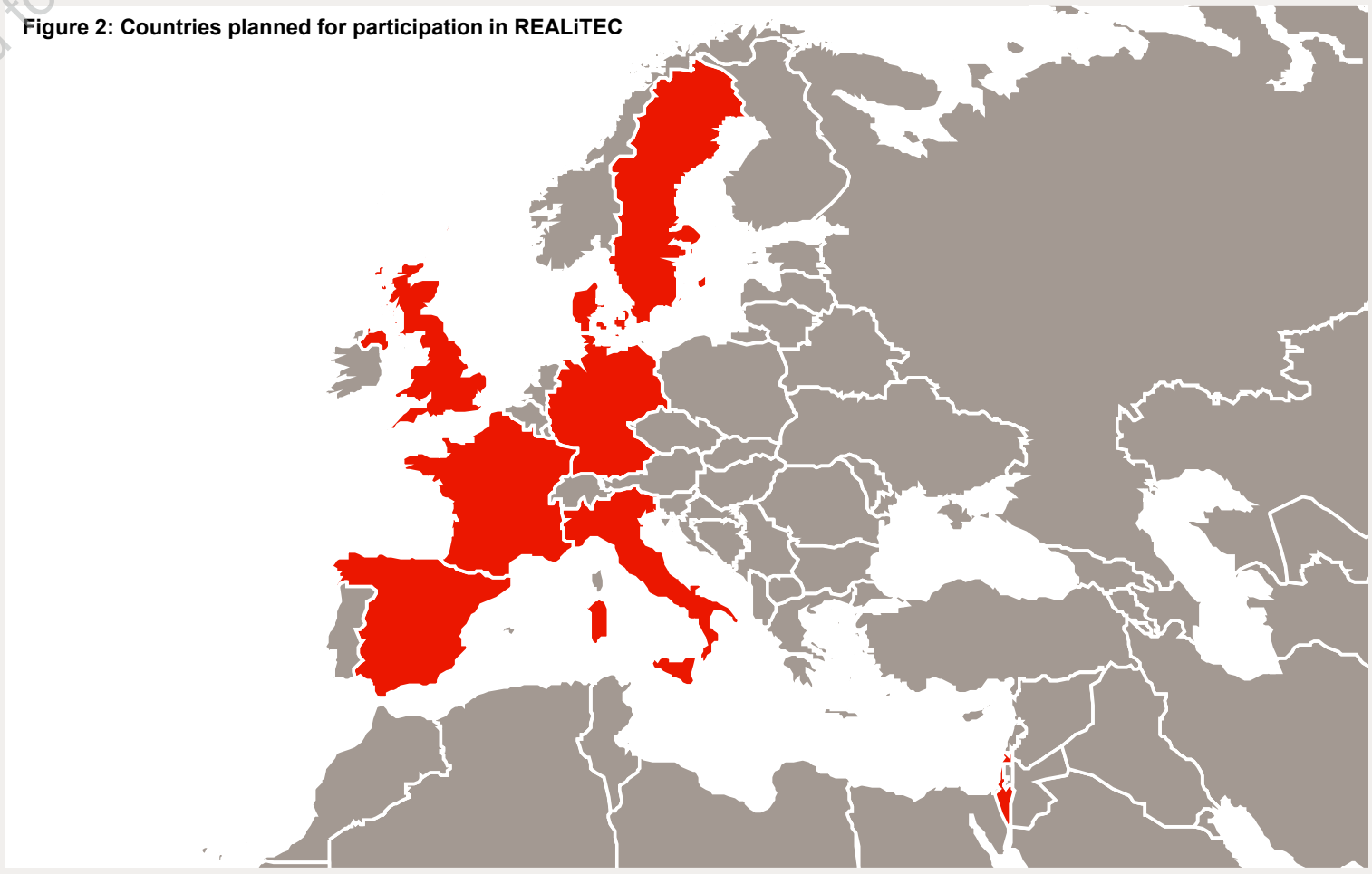
- ≥18 years old with a diagnosis of RRMM
- Received ≥1 dose of teclistamab on or before December 31, 2022
  - As part of pre-approval access programs or in routine clinical practice
- Have not received teclistamab as part of an interventional clinical trial
- Provided informed consent (or an informed consent form waiver for deceased patients)

Outcome measures

• Description of baseline characteristics	• Description of safety management[b]
• ORR[a]	• OS
• Time to first response[a]	• PFS[a]
• Time to best response[a]	• TTNT
• DOR[a]	• MRD
• Description of treatment patterns (eg, healthcare setting, treatment schedules)	

Study conduct will be monitored externally, and eligibility reviewed centrally.
[a]As assessed by the investigator per International Myeloma Working Group response criteria. [b]Incidence 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. MRD, minimal residual disease; TTNT, time to next treatment.

Figure 2: Countries planned for participation in REALiTEC



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