PF770

REALiTEC Subgroup Analysis: A Multi-Country Observational Retrospective Study of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma Outside of Clinical Trials

Rakesh Popat[1], K Martin Kortüm[2], Katarina Uttervall[3], Sarah Leeth Farmer[4], Michele Cavo[5], Bhuvan Kishore[6], Caroline Jacquet[7], Maria Casanova[8], Markus Hansson[9], Katja Weisel[10], Hila Magen[11], Carmine Liberatore[12], Charlotte Toftmann Hansen[13], Moshe Gatt[14], Tamir Shragai[15], Matteo Claudio Da Vià[16], Teresa De Soto Alvarez[17], Mathew Streetly[18], Marc-Steffen Raab[19], Salomon Manier[20], Jesper Aegesen[21], Rana Takchi[22], Peter Hu[23], Diptendu Santra[24], Vadim Strulev[25], Claire Albrecht[26], Eva Rubio-Azpeitia[27], Aurore Perrot[28]

[1]University College London Hospitals NHS Foundation Trust, London, UK; [2]University Hospital of Würzburg, Würzburg, Germany; [3]Kardinska University Hospital, Stockholm, Sweden; [4]Vejle Hospital, Vejle, Denmark; [5]Department of Medical and Surgical Sciences, Bologna University School of Medicine, Bologna, Italy; [6]University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK; [7]Service d'Hématologie, CHU de Nancy, Vandoeuvre-lès-Nancy, France; [8]Hospital Costa del Sol, Marbella, Spain; [9]Sahlgrenska Academy Göteborg University & Sahlgrenska University Hospital, Gothenburg, Sweden; Skane University Hospital, Lund, Sweden [10]University Medical Center Hamburg-Eppendorf, Hamburg, Germany; [11]Chaim Sheba Medical Center, Ramat-Gan, Israel; Sackler Faculty of Medicine and Health Sciences, Tel Aviv University, Tel Aviv, Israel; [12]Ospedale Santo Spirito, Pescara, Italy; [13]Odense University Hospital, Odense, Denmark; [14]Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel; [15]Tel Aviv Sourasky Medical Center, Tel Aviv, Israel; Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; [16]IRCCS Fondazione Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy; [17]La Paz University Hospital, IdiPAZ Research Institute, Madrid, Spain; [18]Guy's Hospital, Guys and St. Thomas' NHS Foundation Trust, UK; [19]University Hospital Heidelberg and Clinical Cooperation Unit Molecular Hematology/Oncology, German Cancer Research Center, Heidelberg, Germany; [20]University of Lille, CHU Lille, Lille, France; [21]Ryhov County Hospital, Jönköping, Sweden; [22]Johnson & Johnson Middle East FZ-LLC; Beirut, Lebanon; [23]Johnson & Johnson, Raritan, NJ, USA; [24]Parexel International, United Kingdom, on behalf of Janssen-Cilag, Issyles-Moulineaux, France; [25]Johnson & Johnson, Beerse, Belgium; [26]Janssen-Cilag, Issyles-Moulineaux, France; [27]Janssen-Cilag, Madrid, Spain; [28]Centre Hospitalier Universitaire de Toulouse, Oncopole, Toulouse, France

Key Takeaway

REALiTEC demonstrates comparable outcomes to MajesTEC-1 in heavily pretreated patients treated outside of clinical trials, with no differences in effectiveness in subgroups who have historically poorer outcomes, confirming teclistamab as a standard of care in a broad patient population

Conclusions

REALiTEC has demonstrated good effectiveness and manageable toxicity in a hard-to-treat RRMM patient population, with better outcomes in patients who achieved deep response (≥VGPR), those eligible for MajesTEC-1, and those without prior exposure to BCMA ADCs

Teclistamab is effective in patients with prior BCMA, with ORR 52.6% and ≥VGPR 47.4%, similar to MajesTEC-1 cohort C. However, prior exposure to BCMA ADCs seemed to adversely affect PFS and OS in our cohort. More data on sequencing BCMA therapies is needed to confirm this finding

Subsequent cohorts of REALiTEC, REALiTEC 2 and 3 will help inform optimal patient management, sequencing, and outcomes in the real world

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Disclosures

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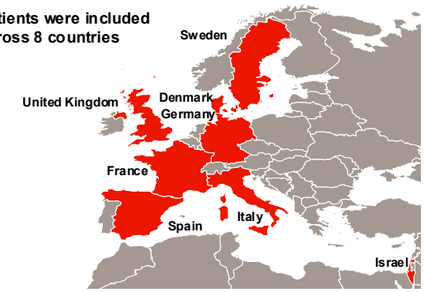
Introduction

- Teclistamab is the first approved bispecific monoclonal antibody targeting B-cell maturation antigen (BCMA) and CD3 for the treatment of patients with triple-class exposed (TCE) relapsed/refractory multiple myeloma (RRMM)[1-3]
- With a median follow-up of 30.4 months, the pivotal phase 1/2 trial MajesTEC-1 (N=165) showed deep and durable responses with teclistamab in patients without prior BCMA-targeted treatment[1,4]
  - Overall response rate (ORR) was 63% with a complete response or better (≥CR) rate of 46.1% and a very good partial response or better (≥VGPR) rate of 59.4%[4]
- In the subgroup analysis of MajesTEC-1[2], patients who were penta-refractory, had high risk cytogenetics, or were aged ≥75 years had similar response rates and compared with the overall study population
- Patients in earlier lines of therapy (≤3 prior lines) had numerically higher median progression-free survival (PFS) and overall survival (OS) compared with the study population[5]
- MajesTEC-1 cohort C also demonstrated promising results in patients exposed to prior BCMA-targeting treatments, with 52.5% ORR, 47.5% ≥VGPR, and 30% ≥CR rates[3]
- Initial effectiveness and safety data from REALiTEC have been previously reported.[6,7] Here, we report the subgroup analysis of the REALiTEC study, a retrospective observational study of patients receiving teclistamab outside of clinical trials

Methods

- REALiTEC is a retrospective, international, noninterventional study that aimed to describe the management and outcomes of patients treated with teclistamab outside of clinical trials
- Informed consent was obtained for all patients
- Data were collected from patient medical records, including demographics, disease characteristics, prior therapies, effectiveness, and safety
- Treatment outcomes included effectiveness and adverse events profile
- REALiTEC included 23 sites across 8 countries (**Figure 1**)

Figure 1: 113 patients were included from 23 sites across 8 countries



Results

Patient disposition

- Overall, 113 patients were included in the study; 100 from preapproval access programs and 13 treated with commercial teclistamab
- Patient baseline characteristics are shown in the **Table**

Table: Baseline demographics and disease characteristics

Characteristic	N=113[a]
Age, years, median (range)	66 (43–86)
<65 years, n (%)	47 (41.6)
≥65 to <75 years, n (%)	49 (43.4)
≥75 years, n (%)	17 (15.0)
Male, n (%)	57 (50.4)
ECOG PS ≥1, n (%)	27/49 (55.1)
ISS stage II or III, n (%)	62 (54.8)
High-risk cytogenetics,[b] n (%)	32/62 (51.6)
Extramedullary plasmacytoma, n (%)	9/59 (15.3)
Patients ineligible for MajesTEC-1, n (%)	78 (69.0)
Years since diagnosis, median (range)	6.88 (0.7–24.2)
Previous lines of therapy, median (range)	6 (2–12)
Triple-class exposed, n (%)	113 (100)
Penta-class exposed, n (%)	100 (88.5)
Triple-refractory, n (%)	89 (78.8)
Penta-refractory, n (%)	50 (44.2)
Refractory to the last line of therapy, n (%)	86 (76.1)
Autologous SCT, n (%)	86 (76.1)
Patients receiving prior BCMA,[c] n (%)	38 (33.6)
Number of therapies	43
CAR-T	10
ADC	32
BsAbs	1

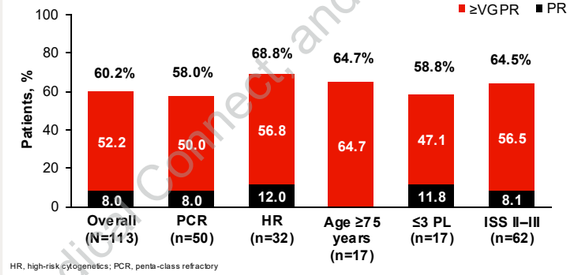
[a]Data available added as denominators if some were missing and not available in the clinical chart for the whole cohort. [b]High risk defined as having presence of t(4;14), t(14;16), del17p13, and amp1q21. [c]38 patients received 43 prior BCMA-directed therapies. ADC, antibody-drug conjugate; BsAB, bispecific antibody; CAR, chimeric antigen receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; SCT, stem cell transplant.

- The 38 patients with prior exposure to BCMA-targeted therapy had a longer median time since diagnosis (9.3 years [range, 0.7–24.2]) vs 6.4 years [range, 2.1–18.5]) than non–BCMA-exposed patients
- Prior BCMA-exposed patients had a median of 6 prior lines (PL) of therapy (range, 3–12) vs 5 PL (range, 2–12) in the non–BCMA-exposed patients, with most having ≥5 PL (89.5% vs 60%)

Response rates

- With a median follow-up of 20.7 months, ORR for the whole cohort was 60.2% with a ≥VGPR rate of 52.2%
- Response rates from subgroups were consistent with the overall patient population and across them, with ORRs ranging from 58–68.8% and ≥VGPR rates from 47.1–64.7% (**Figure 2**)

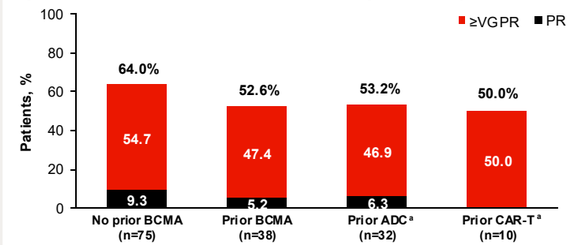
Figure 2: Response rates by subgroups



HR, high-risk cytogenetics; PCR, penta-class refractory

- In patients receiving prior BCMA-targeted therapy, ORR was 52.6% with a ≥VGPR rate of 47.4% (**Figure 3**)
  - For the 32 and 10 patients who received prior ADC or CAR-T, ORR was 53.2% and 50.0%, with ≥VGPR rates of 46.9% and 50%, respectively

Figure 3: ORR with exposure to prior BCMA-targeted therapy



[a]5 patients are included in both the ADC and CAR-T groups, having received both before teclistamab.

Survival outcomes

- In the overall cohort, median DOR was 20.3 (14.8–not evaluable [NE]) months, median PFS was 9.7 (5.5–18.8) months and median OS was 26.2 (16.5–NE) months
- DOR, PFS, and OS were consistent across most subgroups (**Figures 4–6**)
- Patients achieving ≥VGPR had a trend towards longer median DOR (26.1 vs 3.8 months; *P*=0.061), and had significantly longer PFS (not reached [NR] vs 2.6 months; *P*<0.001) and OS (NR vs 6.2 months; *P*<0.001) than those who did not reach VGPR
- Patients who could have been eligible for MajesTEC-1 had significantly longer DOR (NR vs 16.7 months; *P*=0.024), PFS (NR vs 6.5 months; *P*=0.004), and OS (26.3 vs 16.7 months; *P*=0.015) compared with those meeting any ineligibility criteria
- Patients without prior exposure to ADC therapy had a trend towards longer DOR (26.1 vs 16.7 months; *P*=0.083), and had significantly longer PFS (15.7 vs 3.1 months; *P*=0.009) and OS (NR vs 9.9 months; *P*=0.002) compared with those previously exposed

Figure 4: DOR subgroup analysis

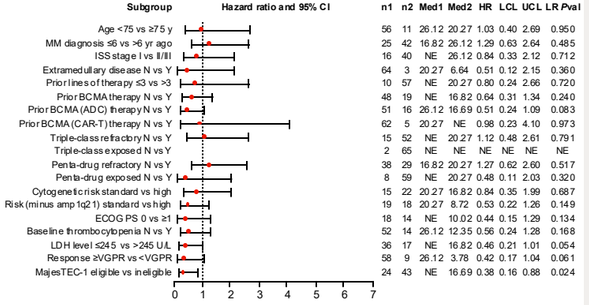


Figure 5: PFS subgroup analysis

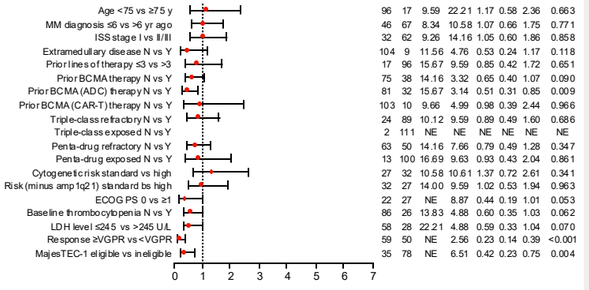
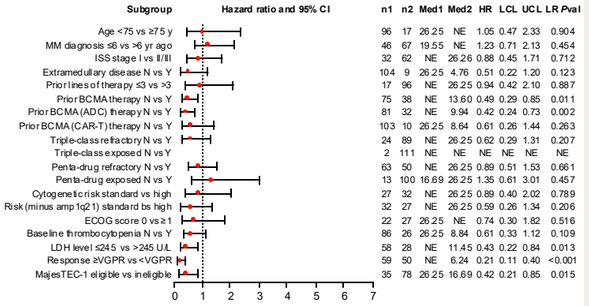


Figure 6: OS subgroup analysis



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Multiple Myeloma

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