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First Results From REALiTAL: A Multi-Country Observational Retrospective Study of Talquetamab in Patients With Relapsed/Refractory Multiple Myeloma Outside of Clinical Trials

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Key Takeaway

Results from the REALiTAL study corroborate those from the MonumenTAL-1 trial

Conclusions

Tal demonstrates deep and durable responses in hard-to-treat, heavily pretreated patients with RRMM who may not have been eligible for clinical trials

Results align with previous studies, in which a deep response to Tal was associated with prolonged DOR, PFS, and OS

No new safety signals were identified; the safety profile was consistent with that previously reported for Tal

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Disclosures

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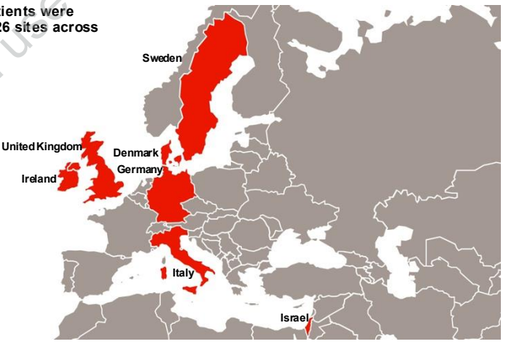
Introduction

- Talquetamab (Tal) is the first G protein–coupled receptor family C group 5 member D (GPRC5D)-targeting bispecific antibody (BsAb) approved for the treatment of patients with relapsed/refractory multiple myeloma (RRMM)[1-3]
- The pivotal phase 1/2 MonumenTAL-1 trial (N=375) followed patients receiving weekly (QW) Tal for a median 29.8 months or Tal every other week (Q2W) for a median 23.4 months[1]
  - Overall response rate (ORR) was 74.1% (QW) and 69.5% (Q2W)
  - Median duration of response (DOR) was 9.5 months (QW) and 17.5 months (Q2W)
  - Median progression-free survival (PFS) was 7.5 months (QW) and 11.2 months (Q2W)
- Here, we report the first results of the REALiTAL study, a retrospective study of patients receiving Tal outside of clinical trials

Methods

- REALiTAL is a retrospective, international, noninterventional study that aims to describe the management and outcomes of patients treated with Tal 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 were assessed based on response rates, time to first and best response, DOR, PFS, and overall survival (OS)
- Responses were evaluated according to International Myeloma Working Group (IMWG) criteria
- REALiTAL included 26 sites across 7 countries (**Figure 1**)

Figure 1: 93 patients were included from 26 sites across 7 countries



Results

Patients

- REALiTAL included 93 eligible patients receiving Tal on or before 31 December 2023; most patients received Tal via preapproval access programs
- Patient baseline characteristics are shown in **Table 1**

Table 1: Baseline demographics and disease characteristics

Characteristic	N=93[a]
Age, years, median (range)	65 (24–86)
<65 years, n (%)	42 (45.2)
≥65 to <75 years, n (%)	37 (39.8)
≥75 years, n (%)	14 (15.1)
Male, n (%)	55 (59.1)
ECOG PS ≥1, n (%)	21/35 (60.0)
ISS stage II or III, n (%)	42/69 (75.4)
High-risk cytogenetics,[b] n (%)	22/48 (72.9)
Extramedullary plasmacytoma, n (%)	11/51 (21.6)
LDH >245 U/L, n (%)	43/80 (53.8)
Patients ineligible for MonumenTAL-1, n (%)	78 (69.0)
Years since diagnosis, median (range)	6.03 (1.5–23.1)
Previous lines of therapy, median (range)	5 (2–16)
Triple-class exposed, n (%)	91 (97.8)
Penta-class exposed, n (%)	80 (86.0)
Triple-refractory, n (%)	65 (69.9)
Penta-refractory, n (%)	37 (39.8)
Refractory to the last line of therapy, n (%)	71 (76.3)
Autologous SCT, n (%)	70 (75.3)
Patients receiving prior BCMA, n (%)	
CAR-T	11 (11.8)
ADC	24 (25.8)
BsAbs	22 (23.7)

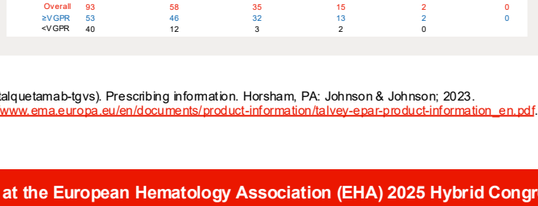
[a]Data available added as denominators if some were missing and not available in the clinical chart for the whole cohort. [b]High risk defined as having presence of t(4;14), t(14;16), del(17p13), and amp1q21. ADC, antibody-drug conjugate; BsAB, bispecific antibody; CAR, chimeric antigen receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; LDH, lactate dehydrogenase; SCT, stem cell transplant.

- Patients were heavily pretreated with a median 5 prior lines of therapy; most (n=80; 86.0%) were penta-class exposed, and almost all (n=91; 97.8%) were triple-class exposed
- 57 (61.3%) patients had previously received anti-BCMA treatments
- 82 (88.2%) patients started Q2W administration; 11 (11.8%) started QW; and 18 (22.0%) switched from Q2W to once monthly (QM) dosing after a median 6 months
  - 12/18 patients who switched from Q2W to QM did so due to disease response
- Median duration of follow-up was 14.95 (range, 0.36–25.26) months
  - 68 (73.1%) patients discontinued treatment; 57 (61.3%) due to disease progression, 5 (5.4%) due to adverse events, and 3 (3.2%) due to physician decision

Efficacy

- ORR was 66.7%, with 53 (57.0%) experiencing a very good partial response (VGPR) or better (**Figure 2**)
- 37 (39.8%) patients experienced a near complete response (a serological complete response [CR] without available bone marrow status[4]) or better
- Median time to first response was 1.2 (95% CI, 0.9–1.3) months; median time to best response was 3.6 (95% CI, 2.7–4.9) months

Figure 2: ORR and overall best response[a]



[a]Based on IMWG 2016 Consensus Criteria. PR, partial response.

- Median DOR was 12.3 (95% CI, 7.9–not estimable [NE]) months, median PFS was 8.2 (95% CI, 6.1–10.7) months, and median OS was 25.3 (95% CI, 17.3–NE) months, over a median treatment duration of 7.9 (95% CI, 5.7–9.9) months (**Figures 3–5**)
  - Patients achieving ≥VGPR had longer median DOR (13.4 vs 6.8 months), PFS (18.2 vs 2.9 months), and OS (25.3 vs 11.5 months) than those achieving <VGPR

Figure 3: DOR by VGPR status

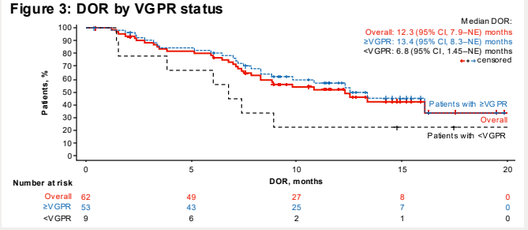


Figure 4: PFS by VGPR status

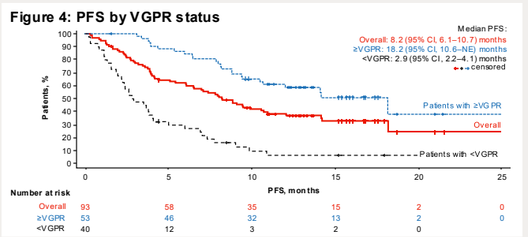
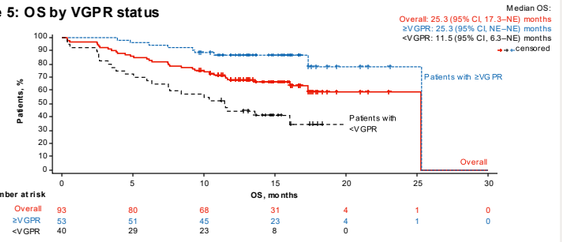


Figure 5: OS by VGPR status



Safety

- The overall safety profile for Tal is shown in **Table 2**

Table 2: TEAEs of clinical interest

TEAE, n (%)	N=93	
	Any Grade, n (%)	Grade 3/4, n (%)
Any TEAE, n (%)	92 (98.9)	28 (30.1)
Infections	44 (47.3)	9 (9.7)
COVID-19	7 (7.5)	1 (1.1)
Pneumonia	6 (6.5)	3 (3.2)
Upper respiratory tract infection	5 (5.4)	0 (0.0)
Urinary tract infection	5 (5.4)	1 (1.1)
Hematological TEAEs		
Anemia	13 (14.0)	8 (8.6)
Neutropenia	9 (9.7)	6 (6.5)
Thrombocytopenia	7 (7.5)	6 (6.5)
Nonhematological TEAEs		
Skin/nail toxicity	63 (67.7)	1 (1.1)
Oral toxicity	62 (66.7)	1 (1.1)
Dysgeusia[a]	53 (57.0)	NA
CRS	52 (55.9)	1 (1.1)
Neurological TEAEs of interest		
ICANS	2 (2.2)	0 (0.0)

[a]Includes dysgeusia, ageusia, and taste disturbance. Maximum grade is 2. CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; NA, not applicable; TEAE, treatment-emergent adverse event.

- The most common TEAEs were skin/nail toxicity, oral toxicity including dysgeusia, CRS, and infections
  - 2 (2.2%) patients interrupted Tal and 1 (1.1%) reduced dose due to oral toxicity; 1 (1.1%) discontinued due to dysgeusia
  - 4 (4.3%) patients interrupted Tal due to skin/nail toxicity; none discontinued treatment due to skin/nail toxicity
  - 75% of skin/nail toxicity events and 58% of oral toxicity events resolved/were resolving at time of data collection
- 26 (28.0%) TEAEs were grade 3/4; 8 (8.6%) fatalities were due to general health deterioration (n=3), disease progression, pneumonia, spontaneous bacterial peritonitis, gastrointestinal hemorrhage, and hypercalcemia
- 9 (9.7%) patients had grade 3/4 infection; 1 (1.1%) discontinued treatment and 2 (2.2%) died due to infection
- CRS and ICANS were mostly grade 1/2; 1 (1.1%) patient had grade 3 CRS
  - All but 1 CRS event resolved/were resolving at time of data collection

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Multiple Myeloma

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