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Safety 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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Introduction and Methods

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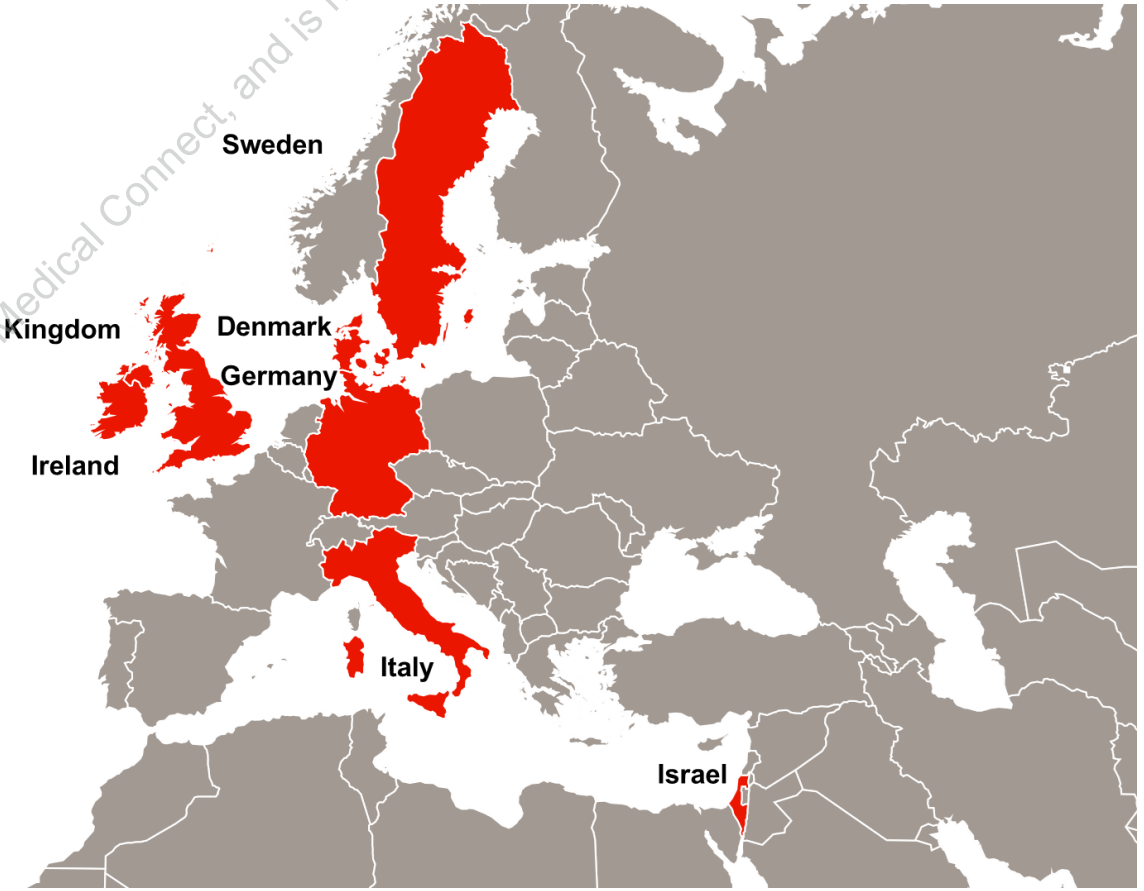
- The phase 1/2 **MonumenTAL-1** study demonstrated that talquetamab elicited deep and durable responses with low discontinuation rates in patients with RRMM
- **REALiTAL** is a retrospective study describing the effectiveness, safety, and therapeutic management of talquetamab in patients treated outside of clinical trials
- Initial efficacy and safety data from REALiTAL were presented at the 2025 EHA Congress and subgroup analyses were presented at the IMS 2025 meeting.
  - ORR 66.7%, similar to MonumenTAL-1
- Here, we describe in detail the safety profile of talquetamab and the therapeutic management observed in REALiTAL



93 patients included across 26 sites in 7 countries, mostly prior to talquetamab commercial availability

EHA, European Hematology Association; IMS, International Myeloma Society; ORR, overall response rate; RRMM, relapsed/refractory multiple myeloma.

1. Rasche L, et al. Presented at ASCO; May 30–June 3, 2025; Chicago, IL, USA & Virtual. Poster 96. 2. TALVEY® (talquetamab-tgvs). Prescribing information. Horsham, PA: Johnson & Johnson; 2023.
3. TALVEY® (talquetamab). Summary of product characteristics. Leiden, Netherlands: Johnson & Johnson; 2024. 4. Uttervall K, et al. Presented at EHA; June 12–15, 2025; Milan, Italy. Poster PF742.

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Baseline Demographics and Disease Characteristics

Characteristic	N=93[a]
Age, years, median (range)	65 (24–86)
ECOG PS ≥1, n (%)	21/35 (60.0)
Extramedullary plasmacytoma, n (%)	11/51 (21.6)
LDH >245 U/L, n (%)	43/80 (53.8)
Creatinine clearance mL/min/1.73 m^2	86
<30 mL/min/1.73 m^2	7 (8.1)
≥30 to <40 mL/min/1.73 m^2	7 (8.1)
≥40 mL/min/1.73 m^2	72 (83.7)
History of severe infections, n (%)	10 (10.8)
Cardiac conditions, n (%)[b]	9 (9.7)
Years since diagnosis, median (range)	6.03 (1.5–23.1)
Previous lines of therapy, median (range)	5 (2–16)
Refractory to the last line of therapy, n (%)	71 (76.3)
Autologous SCT, n (%)	70 (75.3)
Patients receiving prior BCMA, n (%)	57
CAR-T	11 (11.8)
ADC	24 (25.8)
BsAbs	22 (23.7)

- 93 patients; includes patients with comorbidities such as renal or cardiac impairment or a history of severe infections
- 15 months median follow-up
- Starting dosing
  - 88% bi-weekly
  - 12% weekly
- 73% of patients discontinued treatment
  - 61% due to disease progression
  - 5% due to AEs
  - 3% due to physician decision

[a]Data available added as denominators if some were missing and not available in the clinical chart for the whole cohort. [b]Cardiac conditions include myocardial infarction or coronary artery bypass graft.
ADC, antibody-drug conjugate; AE, adverse event; BCMA, B-cell maturation antigen; BsAb, bispecific antibody; CAR, chimeric antigen receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; LDH, lactate dehydrogenase; SCT, stem cell transplant.

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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)	8 (8.6)
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)
Taste changes	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)

- Most common were skin/nail toxicity, oral toxicity, dysgeusia, infections and CRS
- 2 cases of grade 1 ICANS
- No ataxia reported
- 8 (8.6%) deaths, none were considered related to talquetamab

[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.

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Concomitant Medications

CRS management

Concomitant medications, n (%)	Total
Patients receiving ≥1 medication, n (%)	50 (53.8)
AE treatment	41 (44.1)
Tocilizumab	22 (23.7)
Prophylaxis	19 (20.4)

52 (55.9%) patients experienced CRS (all but 1 were grade 1/2)

Infection management

Concomitant medications, n (%)	Total
Patients receiving ≥1 medication, n (%)	77 (82.8)
AE treatment	39 (41.9)
Antibiotics	34 (36.6)
Antiviral	6 (6.5)
Antifungal	2 (2.2)
Prophylaxis, n (%)	65 (69.9)
Antibiotics	48 (51.6)
Antiviral	52 (55.9)
Antifungal	5 (5.4)
IgRT use	42 (45.2)
Primary prophylaxis	35 (37.6)
Secondary prophylaxis	4 (4.3)
Other	3 (3.2)

44 (47.3%) patients experienced infections (8 grade 3/4; 1 grade 5)

Skin/nail toxicity management

Concomitant medications, n (%)	Total
Patients receiving ≥1 medication, n (%)	35 (37.6)
AE treatment	32 (34.4)
Emollients and moisturizers	12 (12.9)
Corticosteroids	19 (20.4)
Antihistamines	5 (5.4)
Prophylaxis	3 (3.2)

63 (67.7%) patients experienced skin- and/or nail-related AEs (all but 1 were grade 1/2)

Oral toxicity and dysgeusia management

Concomitant medications, n (%)	Total
Patients receiving one or more medication, n (%)	28 (30.1)
AE treatment	25 (26.9)
Corticosteroids	9 (9.7)
Anti-infectives	10 (10.8)
Prophylaxis	3 (3.2)

62 (66.7%) patients experienced oral toxicity (all but 1 were grade 1/2)

53 (57%) patients experienced dysgeusia

AE, adverse event; CRS, cytokine release syndrome; IgRT, immunoglobulin replacement therapy.

Conclusions

- The majority of AEs in REALiTAL were clinically manageable, with no new safety signals identified
- Infections were generally low grade and resolved with appropriate management. Taste-related changes and skin/nail reactions were reversible, with most events showing improvement. CRS was mostly low-grade and resolved, with limited use of tocilizumab or prophylactics in the study. ICANS events were rare and low grade, with no grade ≥3 cases reported
- Only 5.4% of patients discontinued treatment due to GPRC5D-related AEs

Treatment with talquetamab outside of clinical trials was generally safe and manageable with similar outcomes to those observed previously in the MonumenTAL-1 study

AE, adverse event; CRS, cytokine release syndrome; GPRC5D, G protein–coupled receptor class C group 5 member D; ICANS, immune effector cell–associated neurotoxicity syndrome.

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