PF742

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

Katarina Uttervall[1], Martin Kortüm[2], Aurore Perrot[3], Vitaliy Mykytiv[4], Hila Magen[5], Elisabetta Antonioli[6], Matteo Claudio Da Via[7], Carmine Liberatore[8], Elena Zamagni[9], Markus Hansson[10], Maurizio Musso[11], Janusz Krawczyk[12], Tamir Shragai[13], Katja Weisel[14], Raphael Teipel[15], DoRota Knut-Bojanowska[16], Charlotte Toftmann Hansen[17], Patrick Hayden[18], Mathias Haenel[19], Marc-Steffen Raab[20], Fabrizio Pane[21], Sarah Leeth Farmer[22], Moshe Gatt[23], Valerio De Stefano[24], Bhuvan Kishore[25], Susanne Strifler[26], Rana Takchi[27], Peter Hu[28], Diptendu Santra[29], Vadim Strulev[30], Eva Rubio-Azpeitia[31], Eric Aeby[32], Krystof Subrt[30], Claire Albrecht[33], Natalia Martin Suñe[34], Rakesh Popat[35]

[1]Karolinska University Hospital, Stockholm, Sweden; [2]University Hospital of Würzburg, Würzburg, Germany; [3]Centre Hospitalier Universitaire de Toulouse, Oncopole, Toulouse, France; [4]Cork University Hospital, Cork, Ireland; [5]Chaim Sheba Medical Center, Ramat-Gan, Israel; [6]Sackler Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel; [7]Careggi Hospital and University of Florence, Firenze, Italy; [8]IRCCS Fondazione Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy; [9]Ospedale Santo Spirito, Pescara, Italy; [10]University of Bologna, Bologna, Italy; [11]Sahlgrenska Academy Göteborg University and Sahlgrenska University Hospital, Gothenburg, Sweden; [12]Skane University Hospital, Lund, Sweden; [13]UOC di Oncoematologia e TMO, Casa di Cura La Madonnina, Palermo, Italy; [14]University Hospital Galway, Galway, Ireland; [15]Tel Aviv Sourasky Medical Center, Tel Aviv, Israel; Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; [16]University Medical Center Hamburg-Eppendorf, Hamburg, Germany; [17]Medizinische Klinik und Poliklinik 1, Universitätsklinikum Carl Gustav Carus an der TU Dresden, Dresden, Germany; [18]Ulsterville Hospital, Ulsterville, Sweden; [19]Odense University Hospital, Odense, Denmark; [20]St. James Hospital, Dublin, Ireland; [21]Innere Medizin IV, Klinikum Chemnitz gGmbH, Chemnitz, Germany; [22]University Hospital Heidelberg and Clinical Cooperation Unit Molecular Hematology/Oncology, German Cancer Research Center, Heidelberg, Germany; [23]Hematology and Hematopoietic Stem Cell Transplant Center, Azienda Ospedaliera Universitaria Federico II, Naples, Italy; [24]Vejle Hospital, Vejle, Denmark; [25]Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel; [26]Catholic University, Fondazione Policlinico A. Gemelli, IRCCS, Rome, Italy; [27]Queen Elizabeth Hospital, Birmingham, UK; [28]Klinikum Nuremberg Nord, Nürnberg, Germany; [29]Johnson & Johnson Middle East, Beirut, Lebanon; [30]Statistics & Decision Science, Johnson & Johnson Innovative Medicine Research & Development, USA; [31]Parexel International, UK, on behalf of Janssen-Cilag, Issy-les-Moulineaux, France; [32]Johnson & Johnson, Beerse, Belgium; [33]Janssen-Cilag, Madrid, Spain; [34]Janssen-Cilag GmbH International Zug, Switzerland; [35]Janssen-Cilag, Issy-les-Moulineaux, France; [36]Johnson & Johnson, Madrid, Spain; [37]University College London Hospitals NHS Foundation Trust, London, UK

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

Please scan QR code

Poster

https://www.congresshub.com/EHA2025/Oncology/Talquetamab/Uttervall

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

Acknowledgments

We thank the patients who participated in the study and their families and caregivers, the physicians and nurses who cared for patients and supported this clinical trial, staff members at the study sites, staff members involved in data collection and analyses, and Danielle Greer of Parexel for statistical analysis. This study was funded by Johnson & Johnson. Medical writing support was provided by Jackie Read and Timothy Connelly for Eloquent Scientific Solutions and funded by Johnson & Johnson.

Disclosures

KU served as an advisor or provided expert testimony for GSK, Johnson & Johnson, Pfizer, and Sanofi; and received honoraria and scientific research funding from Johnson & Johnson.

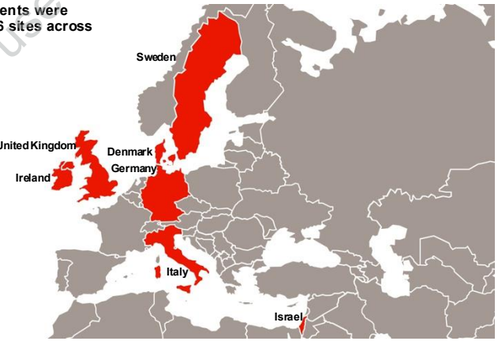
Introduction

- 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 (60.9)
High-risk cytogenetics,[b] n (%)	35/48 (72.9)
Extramedullary plasmacytoma, n (%)	11/51 (21.6)
LDH >245 U/L, n (%)	43/80 (53.8)
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)

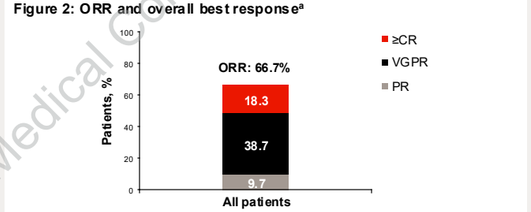
[a]Data available added as denominators if some were missing and not available in the clinical chart for the whole cohort. [b]High risk defined as having presence of t(4;14), t(14;16), del(17p13), and amp1q21. ADC, antibody-drug conjugate; BsAB, bispecific antibody; CAR, chimeric antigen receptor; ECOG 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

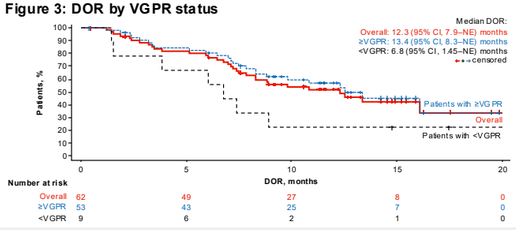


Figure 4: PFS by VGPR status

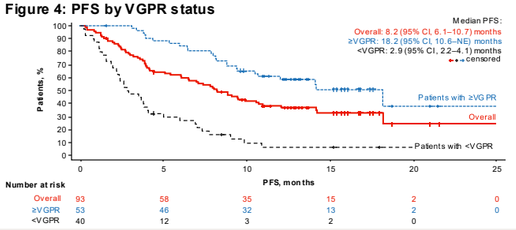
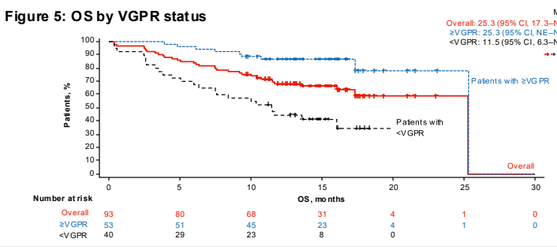


Figure 5: OS by VGPR status



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

References

1. Rasche L, et al. Presented at EHA; June 13–16, 2024; Madrid, Spain. Poster 915. 2. TALVEY® (talquetamab-tgvs). Prescribing information. Horsham, PA: Johnson & Johnson; 2023.
3. TALVEY® (talquetamab). Summary of product characteristics. Johnson & Johnson; 2024. https://www.ema.europa.eu/en/documents/product-information/talvey-epar-product-information_en.pdf.
4. Frenking JH, et al. *HemaSphere*. 2025;9:e70114.

Multiple Myeloma

Presented by K Uttervall at the European Hematology Association (EHA) 2025 Hybrid Congress; June 12–15, 2025; Milan, Italy

This material is distributed by J&J Medical Connect, and is not for promotional use
This material is distributed for scientific purposes only