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Reshaping Treatments: Insights from the BiTAL Study on Talquetamab in Relapsed Refractory Multiple Myeloma.

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Key takeaway

These findings underscore the robust clinical activity of talquetamab in RRMM and emphasize the value of real-world evidence in complementing pivotal trial data to better guide everyday clinical decision-making.

Conclusions

- The preliminary findings from the BiTAL study highlight the effectiveness and safety profile of TAL in the treatment of TCE RRMM outside of clinical trials.
- With an ORR of 78.4% (81.3% Q2W) and a notable 60.8% (63.6% Q2W) of patients achieving VGPR or better, our results demonstrate encouraging depth of response.
- Observed PFS and OS outcomes support the long-term benefit of TAL treatment.
- The safety profile and the relatively low rate of treatment discontinuation due to adverse events further reinforce the treatment's tolerability and manageability in this heavily pre-treated population.

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Poster

https://www.congresshub.com/Oncology/IMS2025/Talquetamab/Rodriguez-Otero

Disclosure declaration

Marcos Lorenzo Pérez received honoraria for lectures from and served on the advisory boards of Janssen, Sanofi, Abbvie, and Beigene. Elena Fernández Poveda received travel and accommodation grants from Janssen, Amgen, and Abbvie. José María Sánchez Pina received travel and accomodation grants from Gilead and Takeda, and honoraria for consulting and advisory roles from Johnson and Johnson and Amgen. Ana Sánchez Quintana received honoraria for lectures from Janssen, Amgen, BMS, and Sanofi. Miriam González Pardo is an employee at Johnson and Johnson and received honoraria, research funding, travel, and accommodation grants from Johnson and Johnson. MªJesús Blanchard received honoraria for consulting and advisory roles from Sanofi, Johnson and Johnson, and Pfizer. Ana Pilar Gonález received honoraria for lectures from and served on the advisory boards of Takeda, BMS/Celgene, Johnson, Astra Zeneca, Sobi, Jazz, Novartis, Sanofi. Sunil Lakhwani received honoraria for lectures from Johnson & Johnson, Novartis, Sanofi, Amgen and The Binding Site and served on the advisory boards of Johnson & Johnson, Novartis, Pfizer and BMS. Juan Luis Reguera received honoraria for lectures from and served on the advisory boards of Kite/Gilead, Novartis and Johnson and Johnson. Speaking bureau from Amgen, BMS, Sanofi, Kite/Gilead and Johnson and Johnson.

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Introduction

- Multiple myeloma (MM) is not currently curable but can be effectively managed for years. New drugs developed over the past two decades have significantly improved prognosis, but complete eradication of the disease remains a formidable challenge due to its complex nature and potential for relapse.
- The clinical management of MM frequently becomes a long-term endeavor, thereby reinforcing the imperative for sustained investigative efforts and the development of novel therapeutic strategies to effectively address the disease's biological complexity and evolving resistance mechanisms. Furthermore, it is relevant to complement research findings with real-world clinical data to support evidence-based decision-making in routine practice.
- Heavily pretreated relapsed/refractory multiple myeloma (RRMM), refractory to all 3 major drug classes, including immunomodulatory drugs (IMiDs), proteasome inhibitors (PI), and anti-CD38 monoclonal antibodies (mAbs), presents a poor prognosis, with a median progression-free survival (PFS) of 4.6 months (95% CI 4.1-5.7) and an overall survival (OS) of 14.8 mo (95% CI 11.8-18.1) highlighting the need for new therapeutic options.[1]
- Talquetamab (TAL), a pioneering bispecific antibody targeting GPRC5D, received approval in Europe in August 2023. Before this, in November 2022, TAL was made accessible to adult patients through pre-approval access programs (PAA) in Spain after reviewing for program eligibility based on specified PAA treatment guidelines.
- The objective of this research is to present preliminary results on demographics, treatment history, efficacy and clinical outcomes of the patients included in the study at the programmed data cut-off (March 2025).

Methods

- This retrospective, non-interventional, observational study is currently ongoing across 64 sites in Spain as of the data cut-off. The data presented were extracted from patient medical records during the chart review period, which spanned from September 2024 to March 2025.
- Adult (≥18 years) patients, diagnosed with TCE RRMM, who had initiated treatment with TAL monotherapy (at least one dose) outside clinical trials through PAA in Spain and had received the first dose of TAL in monotherapy at least 30 days before study initiation were included in the study after, for living patients, signing an Informed Consent Form (ICF).
- Responses were evaluated according to International Myeloma Working Group (IMWG) criteria.
- Quantitative variables are described using measures of central tendency and dispersion (mean, standard deviation [SD], median, range [min-max]). Qualitative variables are described using absolute and relative frequencies (N, %).

Results

Patient demographic and clinical characteristics

- At database cut-off, a total of 148 patients were evaluable and analyzed for this interim analysis. Of these, 111/129 (n/N) (75.0%) received a biweekly initial dosage regimen (Q2W) (**Table 1**), following TAL Summary of Product Characteristics.
- The population was heavily pre-treated with a median of 4 prior lines of therapy.
- Approximately 20-30% of the patients with ECOG≥2 and Charlson ≥2 or frail.
- All patients were triple-class exposed and refractory, and most (68.9%) were penta-class exposed (**Table 1**).

Table 1. Patients' demographic and clinical characteristics at talquetamab initiation

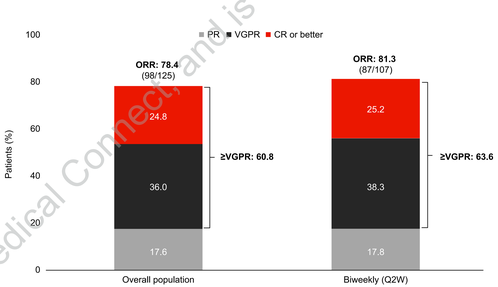
Characteristics	Overall population (N = 148)[a]	Biweekly (Q2W) (N = 111)[a]
Age (years), median (range)	66.5 (40.0-84.0)*	67.0 (40.0-84.0)
65-75 years, n/N (%)	57/138 (41.3)	43 (38.7)
> 75 years, n/N (%)	22/138 (15.9)	19 (17.1)
Female, n/N (%)	71/139 (51.1)	58 (52.3)
ECOG, n/N (%)		
0-1	93/118 (78.8)	75/95 (78.9)
≥2	25/118 (21.2)	20/95 (21.1)
Charlson Index, n/N (%)		
0-1	106/137 (77.4)	85 (76.6)
≥2	31/137 (22.5)	26 (23.4)
Frailty[b], n/N (%)		
Fit+Intermediate	73/117 (49.3)	48/80 (60.0)
Frail	44/117 (37.6)	32/80 (40.0)
CRAB, n/N (%)	120/132 (90.9)	97/108 (89.8)
ISS Stage, n/N (%)		
I	36/116 (31.0)	33/95 (34.7)
II	46/116 (39.7)	33/95 (34.7)
III	34/116 (29.3)	29/95 (29.7)
High risk cytogenetics[c], n/N (%)	12/40 (30.0)	11/30 (36.7)
Extramedullary plasmacytoma, n/N (%)	21/68 (30.9)	17/55 (30.9)
Creatinine clearance, n/N (%)		
<30 mL/min	12/121 (9.9)	8/99 (8.1)
≥30 to <60 mL/min	24/121 (19.8)	21/99 (21.2)
Patients ineligible for MonumenTAL-1[d], n/N (%)	57/109 (52.3)	44/89 (49.4)
Years since diagnosis, median (range)	5.1 (0.7-25.3)[#]	5.2 (0.7-25.3)[$]
Previous lines of therapy, median (range)	4.0 (1.0-9.0)^	4.0 (1.0-9.0)[&]
Triple-class exposed, n/N (%)	135/135 (100)	110/110 (100)
Penta-class exposed, n/N (%)	93/135 (68.9)	74/110 (67.3)
Triple refractory, n/N (%)	105/105 (100)	86/86 (100)
Penta refractory, n/N (%)	34/125 (27.2)	24/104 (23.1)
Autologous SCT, n/N (%)	98/134 (73.1)	78/110 (70.9)
Patients receiving prior BCMA, n/N (%)	47/135 (34.8)	40/110 (36.4)
CAR T	4/47 (8.5)	4/40 (10.0)
Belantamab	37/47 (78.7)	33/40 (82.5)
BCMA BsAbs	6/47 (12.8)	3/40 (7.5)

[a]Data available added as denominators (n/N) if some were missing and not available in the clinical chart for the whole cohort. [b]Fragility assessment was performed retrospectively using age, CCI and ECOG PS score, Facon et al. Leukemia 2020;34:224–33. [c]"del(17p)", "t(4;14)" or "t(14;16)". [d]Main reasons for ineligibility were non-measurable disease, creatinine clearance <40 mL/min and hemoglobin level <8g/dL. ECOG: Eastern Cooperative Oncology Group; ISS: International Staging System; SCT: stem cell transplant; BsAbs: bis-pecific antibodies; del: deletion; t: translocation. *N = 138, [#]N = 126, [$]N = 108, ^N = 134, [&]N = 110.

Efficacy analysis

- The overall population response rate (ORR) was 78.4%, including 24.8% patients who achieved a complete response or better (≥CR), 36.0% a very good partial response (VGPR), and 17.6% a partial response (PR) (**Figure 1**).
- The Q2W group ORR was 81.3%, including 25.2% patients who achieved a ≥CR, 38.3% a VGPR, and 17.8% a PR (**Figure 1**).
- Bone Marrow was not performed in all patients for confirmation of the CR, but the percentage of patients with negative serum and urine electrophoresis and immunofixation was 66.7% and 63.4% of patients in the overall and Q2W groups, respectively.

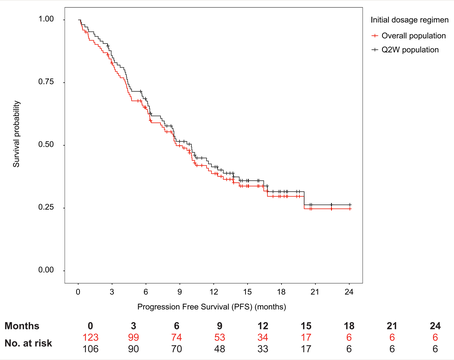
Figure 1. ORR and overall best response rates



Due to rounding and not available data, individual response rates may not sum to the total. ORR: overall response rate; PR: partial response; VGPR: very good partial response; CR: complete response.

- With a median (range) follow-up time for the overall population of 10.8 (0.2-26.2) months, the median progression-free survival (PFS) was 8.67 (SD 1.15, 95% CI 6.42-10.92) months, and mean PFS was 11.56 (SD 0.83, 95% CI 9.92-13.20) (**Figure 2**) (**Table 2**).
- In Q2W patients, median (range) time to follow-up was 12.8 (0.2-26.2) months, the median PFS was 10.02 (SD 1.56, 95% CI 6.97-13.08) months, and mean PFS was 12.15 (SD 0.88, 95% CI 10.41-13.88) (**Figure 2**) (**Table 2**).

Figure 2. PFS (months) of talquetamab treatment in the overall population (N = 123) and in patients with a biweekly initial dosage regimen (Q2W) (N = 106)



- Overall population had a median overall survival (OS) of 26.19 (SD 4.49, 95% CI 17.38-34.99) months, and a mean OS of 17.59 (SD 0.99, 95% CI 15.64-19.53). The Q2W group presented the same values for median OS, while mean OS was 18.21 (SD, 1.01, 95% CI 16.22-20.19) (**Figure 3**) (**Table 2**).

Figure 3. OS (months) of talquetamab treatment in the overall population (N = 123) and in patients with a biweekly initial dosage regimen (Q2W) (N = 106)

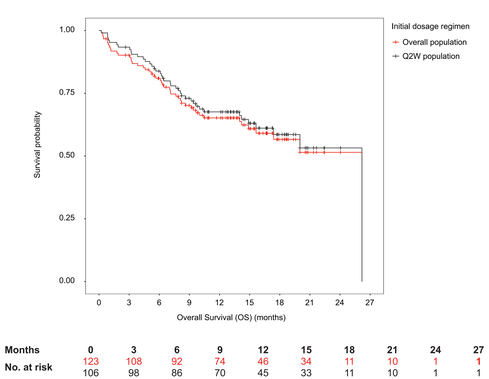


Table 2. Efficacy outcomes

Outcome (months)	Overall population (N = 123)	Biweekly (Q2W) (N = 106)
Follow-up		
Median (range)	10.8 (0.2-26.2)	12.8 (0.2-26.2)
PFS		
Median (95% CI)	8.67 (6.42-10.92)	10.02 (6.97-13.08)
OS		
Median (95% CI)	26.19 (17.38-34.99)	26.19 (17.38-34.99)

CI: confidence interval; PFS: progression-free survival; OS: overall survival.

Safety

- The median (range) duration of TAL treatment was 7.6 months (0.1-22.4) in the overall population, and 8.2 (0.1-22.4) in Q2W.
- At database cut-off, 66.7% (84/126) of patients had permanently discontinued treatment with TAL in the overall population, 42/82 (51.2%) due to disease progression, and 5/82 (6.1%) due to adverse events.
- For those on the Q2W group, 67.0% (73/109) of patients had permanently discontinued treatment with TAL, 39/73 (53.4%) due to disease progression, and 5/73 (6.8%) due to adverse events.
- There was a total of 50 deaths at last status. Twenty-six out of 50 died during therapy or within 30 days after last TAL dose. Main causes of death were disease progression (25/26, 96.2%) and adverse event (1/26, 3.8%)..
  - For Q2W patients, 24/43 (55.8%) patients died during treatment with TAL or within 30 days after discontinuation of the drug. Main reasons for death in this group were also disease progression (23/24, 95.8%), and adverse event (1/24, 4.2%).

Table 3. Adverse events characteristic of GPRC5D T-cell redirection therapy

AEs, n (%)*	Overall population (N = 148)	
	Any grade	Grade ≥ 3
CRS event	88 (59.5)	5 (3.4)
ICANS event	12 (8.1)	3 (2.0)
Infection event	77 (52.0)	20 (13.5)
Weight loss event	15 (10.1)	2 (1.4)
Dysgeusia event	69 (46.6)	0 (0)
Skin-related event[$]	106 (71.6)	4 (2.7)
Nail-related event[^]	61 (41.2)	0 (0)

Grade according to ASTCT scales for CRS and ICANS. For the rest of the AEs, grade according to NCI-CTCAE v5.0. *Patients with at least one event. [$]Considering any of the following events (at least one): Skin rash: maculopapular rash, erythema, erythematous rash; and non-eruptive skin reactions: skin exfoliation, dry skin, pruritus and palmo-plantar erythrodysesthesia syndrome, alopecia. ^Consi-dering any of the following events (at least one): Nail discoloration, nail disorders, onycholysis, onychomadesis, onycholysis, nail dys-trophy, nail toxicity, and nail ridges. AE: adverse event; CRS: cytokine release syndrome; ICANS: immune effector cell-associated neu-rotoxicity syndrome.

References: 1. Weisel K, et al. Outcomes in TCE RRMM patients treated with real-life SOC therapies in LocoMMotion and MOMMENT final data. *EHA 2025*, Abstract PS1783.

Multiple myeloma