REAL-WORLD OUTCOMES OF TALQUETAMAB IN MONUMENTAL-1 TRIAL-INELIGIBLE VERSUS TRIAL-ELIGIBLE PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)

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INTRODUCTION

Talquetamab is a GPRC5D × CD3 bispecific T-cell engager with demonstrated activity in heavily pretreated RRMM in the MonumenTAL-1 study.

The efficacy of talquetamab among patients who would have been trial-ineligible, particularly after prior BCMA-directed therapy, remains clinically relevant as T-cell-redirecting therapies are used earlier in the treatment course.

OBJECTIVES

Primary Objective

Compare talquetamab efficacy by retrospective MonumenTAL-1 eligibility

Secondary Objective

Evaluate outcomes after prior BCMA-directed therapy

Describe real-world safety and treatment feasibility

METHOD

Design: Single-center retrospective cohort
Setting: Moffitt Cancer Center, May 2023–November 2025
Population: 95 patients with RRMM; CAR-T bridging cases excluded
MonumenTAL-1 eligibility retrospectively adjudicated using published criteria
Responses assessed per IMWG criteria
Primary endpoint: ORR
Secondary endpoints: PFS, OS, DOR, safety
Kaplan-Meier/log-rank for time-to-event outcomes; Fisher's exact test for ORR

CONCLUSIONS

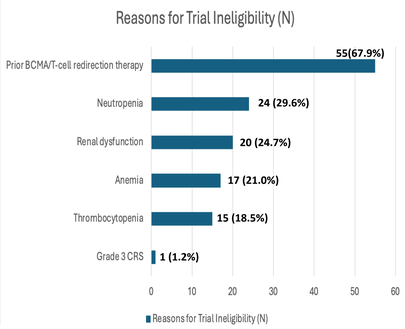
85.3% of patients would not have met MonumenTAL-1 eligibility criteria despite largely preserved performance status (**96.8% ECOG ≤2**).

ORR was preserved across eligibility groups; PFS and OS were unexpectedly longer among patients who would not have met trial criteria.

Survival differences are **hypothesis-generating** given the marked group imbalance (n = **14 vs n = 81**) and potential **physician treatment selection/selection bias**.

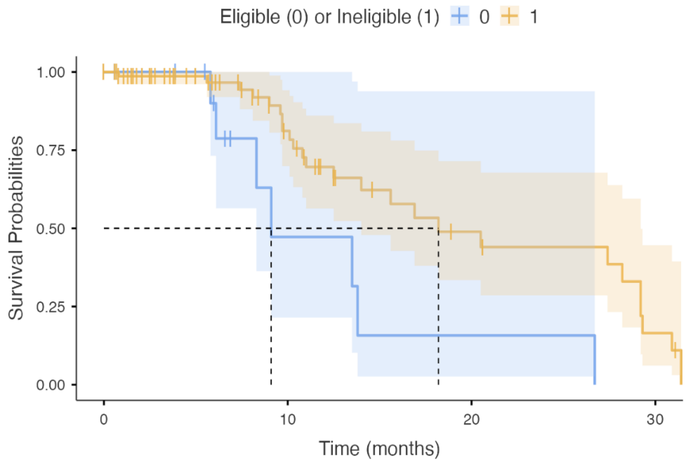
RESULTS

Characteristic	Overall Cohort
N	95
Median age	67 years
Median prior lines	7
Median follow-up	9.7 months
ECOG ≤2	92/95 (96.8%)
ECOG ≤1	71/95 (74.7%)
Would meet MonumenTAL-1 criteria	14 (14.7%)
Would not met criteria	81 (85.3%)



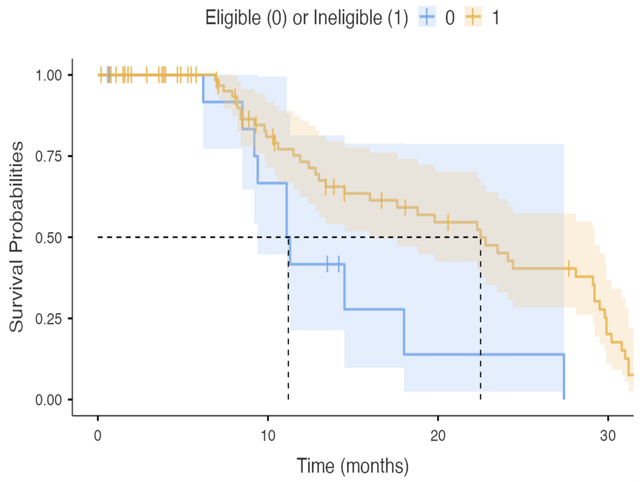
*Patients could meet >1 ineligibility criterion

Progression-Free Survival by Retrospective MonumenTAL-1 Eligibility



Median PFS
- Would meet criteria: **9.1 months**
- Would not meet criteria: **18.2 months**
  - **Log-rank p=0.005**

Overall Survival by Retrospective MonumenTAL-1 Eligibility



Median OS
- Would meet criteria: **11.2 months**
- Would not meet criteria: **22.5 months**
  - **Log-rank p=0.009**

ORR was similar between patients who would and would not have met the MonumenTAL-1 eligibility criteria.

Prior BCMA Exposure: Sequencing Analysis

	No Prior BCMA	Prior BCMA
N	11	84
Median PFS	12.5 m	16.9 m
Log-Rank		p = 0.193
Median OS	13.4 m	22.3 m
Log-Rank		p = 0.137

No statistically significant difference in PFS or OS by prior BCMA exposure

Safety & Real-World Feasibility

CRS: **38/95 patients (40.0%)**
Grade ≥3 CRS: **3/95 (3.2%)**
- Grade 3: **2**
- Grade 4: **1**

Median CRS grade: **2**
Mean CRS-related hospitalization: **2.9 days**
Prophylactic tocilizumab administered: **38/95**
16 patients underwent outpatient step-up initiation
13/16 (81.3%) outpatient patients received prophylactic tocilizumab

CONTACT INFORMATION

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