# Real-World Evidence on Patient-Reported Outcomes Among Newly Diagnosed Multiple Myeloma Patients Treated With Daratumumab-Based Regimens in Frontline

Smith Giri[1], Liton Francisco[1], Nicole Rafalko[2,3], Niodita Gupta-Werner[3], Joshua Richman[4], Smita Bhatia[1], Kelly Godby[1], Gayathri Ravi[1], Susan Bal[1], Marjohn Armoon[3], Rohan Medhekar[3], Luciano J Costa[1]

[1]Division of Hematology and Oncology, Department of Medicine, University of Alabama at Birmingham, Birmingham, AL, USA; [2]Drexel University, Philadelphia, PA, USA; [3]Janssen Scientific Affairs, LLC, a Johnson & Johnson company, Horsham, PA, USA; [4]Department of Surgery, University of Alabama at Birmingham, Birmingham, AL, USA
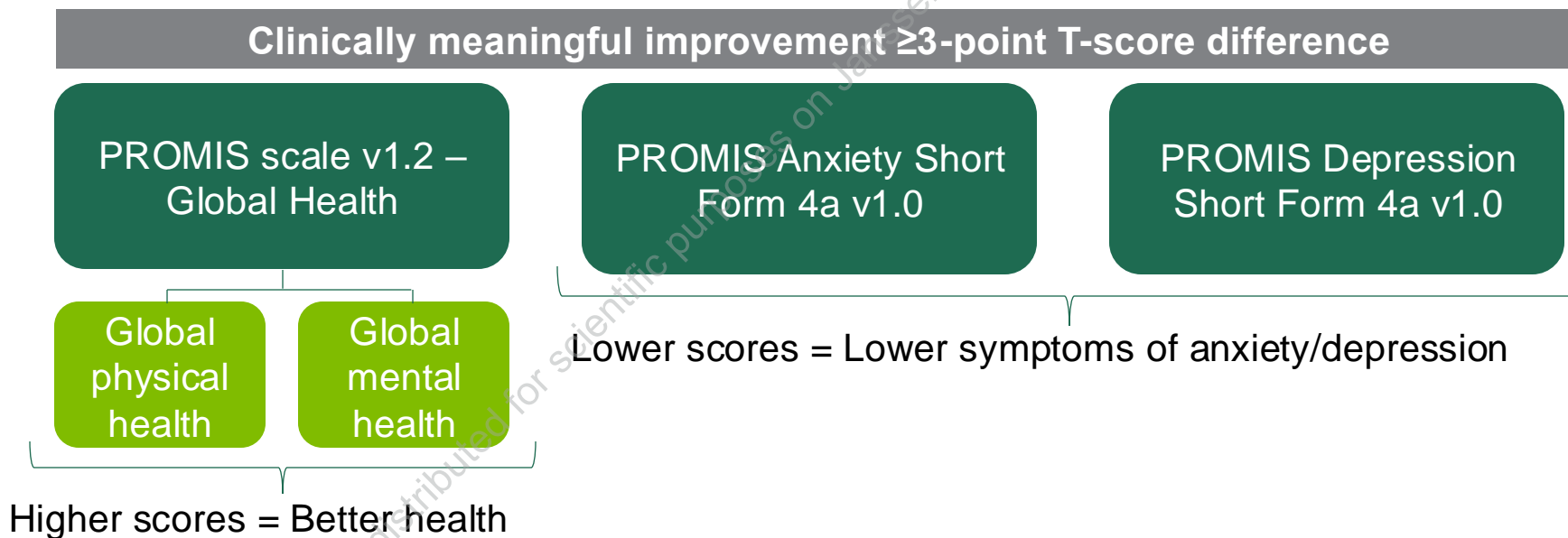
# Introduction

- Patients with multiple myeloma have a high symptom burden that leads to increased rates of anxiety and depression that negatively impacts HRQoL[1-4]

- Daratumumab (Dara)-based regimens have demonstrated clinical efficacy and improvements in HRQoL in both TE and TIE patients with NDMM in randomized clinical trials[5-14]; however, the impact of these regimens on PROs in the real world is not known

- This study examined PROs among patients with TE, TIE, or TD NDMM initiating these regimens as frontline therapy in the real world

Dara, daratumumab; HRQoL, health-related quality of life; NDMM, newly diagnosed multiple myeloma; PRO, patient-reported outcome; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.
1. Sherman AC, et al. *Bone Marrow Transplant* 2004;33:955-62. 2. Alobaidi A, et al. *Support Care Cancer* 2020;28:4097-106. 3. Mols F, et al, *Eur J Haematol* 2012;89:311-9. 4. Kent E, et al. *Cancer* 2015; 121:758-65. 5. Facon T, et al. *N Engl J Med* 2019;380:2104-15. 6. Facon T, et al. *Lancet Oncol* 2021;22:1582-96. 7. Mateos MV, et al. *Lancet* 2020;395:132-41. 8. Mateos MV, et al. *N Engl J Med* 2018;378:518-28. 9. Voorhees PM, et al. *Blood* 2020;136:936-45. 10. Moreau P, et al. *Lancet* 2019;394:29-38. 11. Sonneveld P, et al. *N Engl J Med* 2024;390:301-13. 12. Perrot A, et al. *J Clin Oncol* 2021; 39:227-37. 13. Knop S, et al. *BMC Cancer* 2021;21:659. 14. Roussel M, et al. *Lancet Haematol* 2020;7:e874-83.

# Methods

- PROs were captured as part of the University of Alabama at Birmingham CARE-Heme registry

- PROs were collected between January 2020 and April 2024 among TE and TIE/TD patients with NDMM initiating frontline treatment with Dara-based regimens



**Clinically meaningful improvement ≥3-point T-score difference**

PROMIS scale v1.2 – Global Health

PROMIS Anxiety Short Form 4a v1.0

PROMIS Depression Short Form 4a v1.0

Global physical health

Global mental health

Lower scores = Lower symptoms of anxiety/depression

Higher scores = Better health

CARE-Heme, Cancer and Aging Resilience Evaluation in Hematologic Malignancies; Dara, daratumumab; NDMM, newly diagnosed multiple myeloma; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.
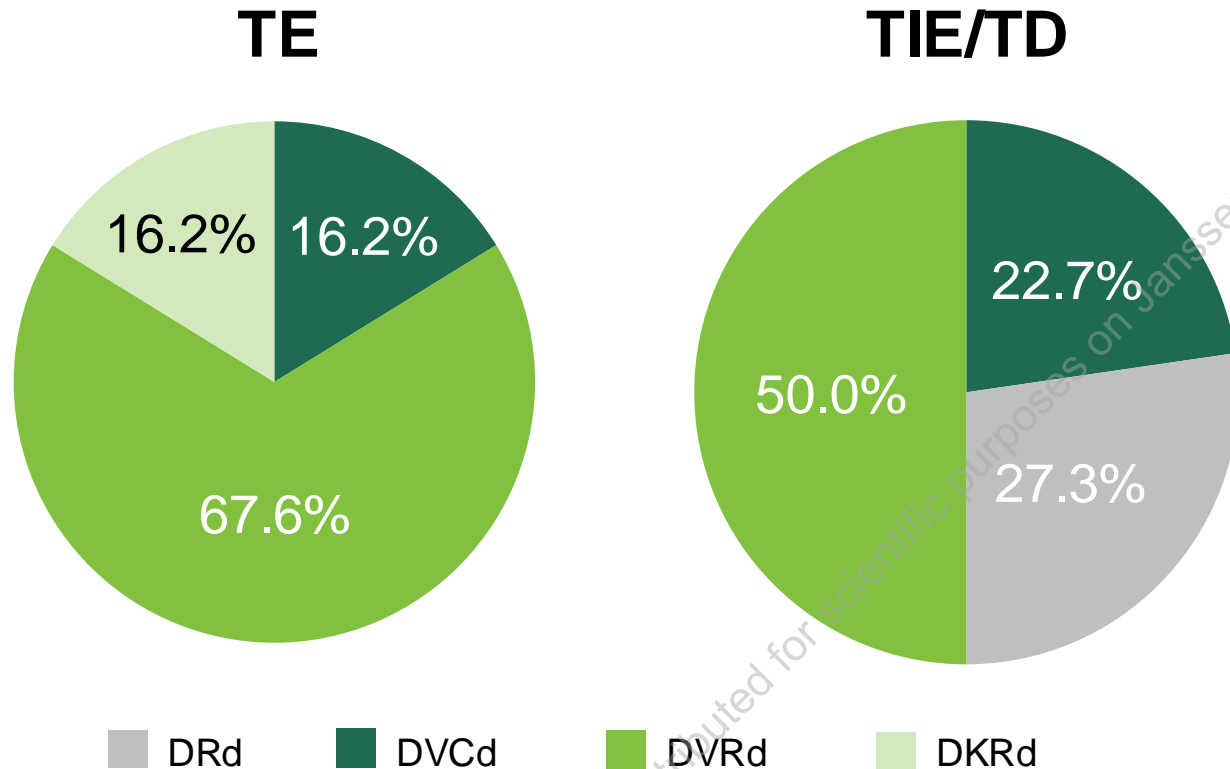
# Demographics and Baseline Characteristics

| | TE (n=37) | TIE/TD (n=44) |
|---|---|---|
| **Age group, n (%)** | | |
| <65 years | 19 (51.4) | 8 (18.2) |
| 65 to <75 years | 17 (45.9) | 19 (43.2) |
| 75 to <85 years | 1 (2.7) | 10 (22.7) |
| ≥85 years | 0 | 7 (15.9) |
| **IMWG frailty index, n (%)** | | |
| Robust/fit | 19 (51.4) | 4 (9.1) |
| Intermediate frail | 11 (29.7) | 16 (36.4) |
| Frail | 7 (18.9) | 17 (38.6) |
| Missing | 0 | 7 (15.9) |
| **Quan-Charlson Comorbidity Index, n (%)** | | |
| 0–1 | 25 (67.6) | 17 (38.6) |
| 2 | 5 (13.5) | 2 (4.5) |
| ≥3 | 7 (18.9) | 20 (45.5) |
| Unknown | 0 | 5 (11.4) |
| **ECOG PS, n (%)** | | |
| 0–1 | 31 (83.8) | 21 (47.7) |
| **PROs, mean baseline T-score (std)** | | |
| PROMIS physical health | 45.2 (8.1) | 39.5 (8.4) |
| PROMIS mental health | 49.1 (9.2) | 46.3 (8.6) |
| PROMIS anxiety | 50.0 (8.6) | 51.5 (9.8) |
| PROMIS depression | 48.6 (8.3) | 50.1 (8.9) |

ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; TD, transplant deferred; TE, treatment eligible; TIE, transplant ineligible.

# Treatment Regimens

**TE**

**TIE/TD**

TE pie chart:
- 16.2% DVCd
- 16.2% DKRd
- 67.6% DVRd

TIE/TD pie chart:
- 22.7% DVCd
- 27.3% DRd
- 50.0% DVRd

Legend: DRd | DVCd | DVRd | DKRd

- All TE patients received quadruplet regimens, as did 72.7% of TIE/TD patients
- DVRd was the most common regimen in both cohorts

DKRd, daratumumab, carfilzomib, lenalidomide, and dexamethasone; DRd, daratumumab, lenalidomide, and dexamethasone; DVCd, daratumumab, bortezomib, cyclophosphamide, and dexamethasone; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.
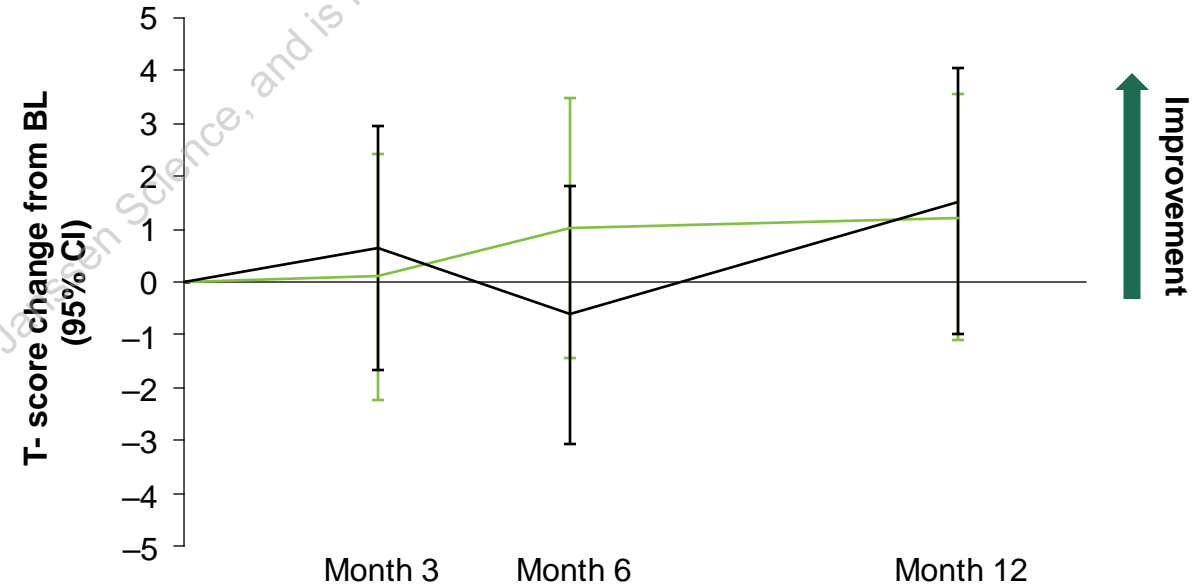
# PROMIS Physical and Mental Health

**PROMIS physical health**
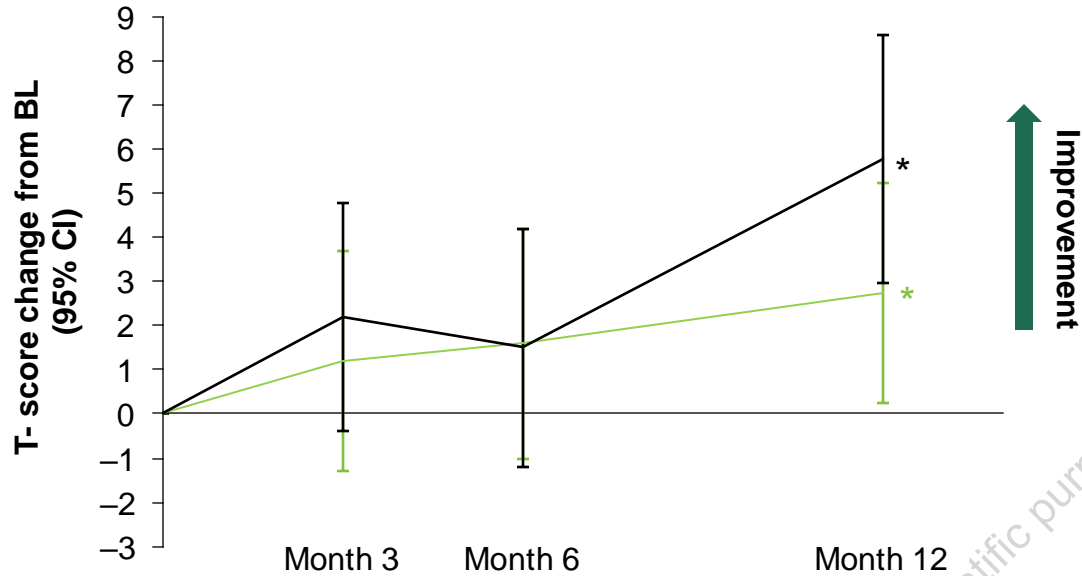
**PROMIS mental health**

**No. of patients**

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 37 | 32 | 37 |
| TIE/TD | 37 | 33 | 29 |

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 36 | 31 | 37 |
| | 39 | 33 | 30 |

**Proportion of patients with clinically meaningful improvement**

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 46% | 47% | 43% |
| TIE/TD | 41% | 33% | 55% |

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 22% | 29% | 35% |
| | 23% | 15% | 23% |

*P<0.05 vs BL. BL, baseline; PROMIS, Patient-Reported Outcomes Measurement Information System; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.

# PROMIS Anxiety and Depression

**PROMIS anxiety**

**PROMIS depression**

**No. of patients**
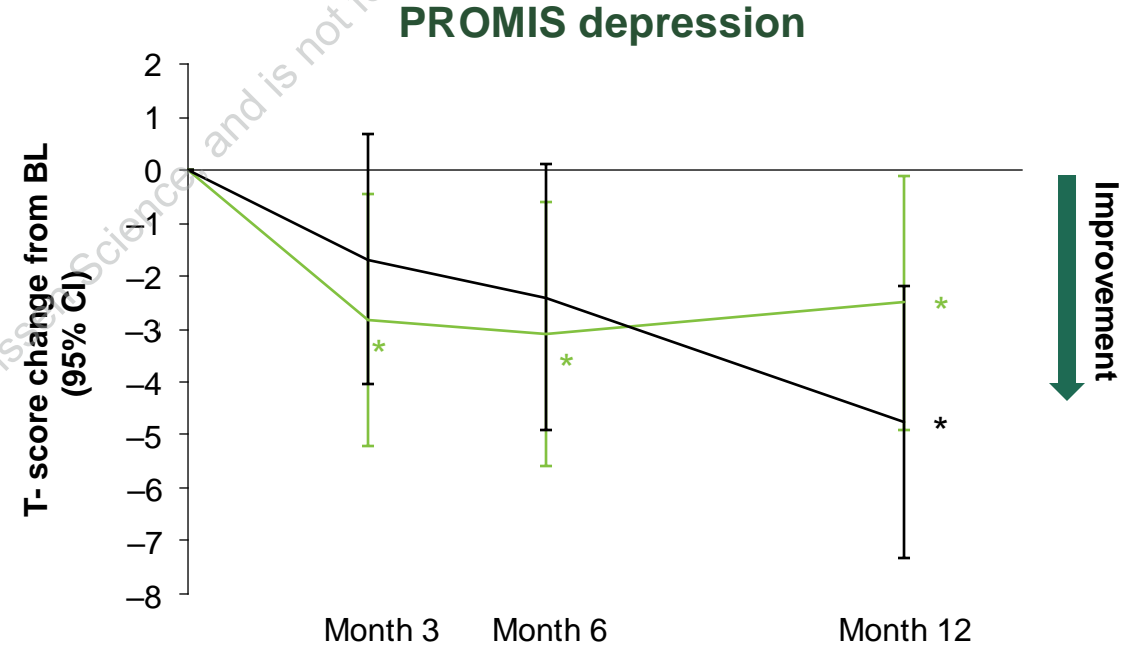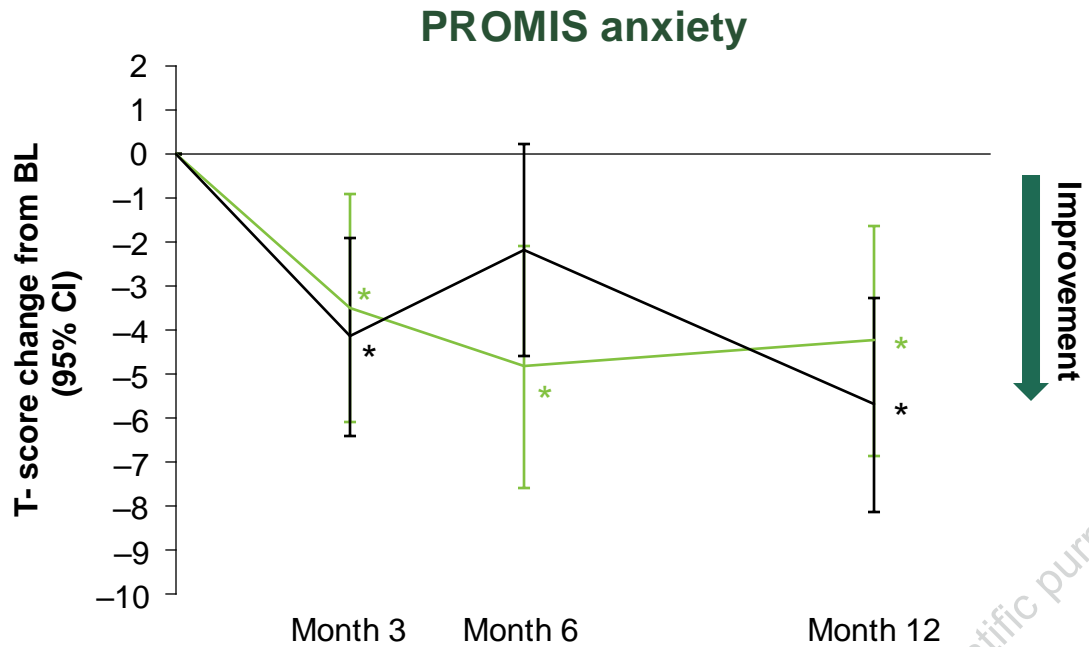
| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 37 | 31 | 36 |
| TIE/TD | 39 | 33 | 31 |

**Proportion of patients with clinically meaningful improvement**

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 43% | 45% | 39% |
| TIE/TD | 38% | 27% | 48% |

**No. of patients** (depression)

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 37 | 32 | 36 |
| TIE/TD | 40 | 34 | 31 |

**Proportion of patients with clinically meaningful improvement** (depression)

| | Month 3 | Month 6 | Month 12 |
|---|---|---|---|
| TE | 30% | 41% | 28% |
| TIE/TD | 25% | 29% | 35% |

*$P<0.05$ vs BL.
BL, baseline; PROMIS, Patient-Reported Outcomes Measurement Information System; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.

# Conclusions

- TIE/TD patients had greater improvements in physical health, anxiety, and depression than TE patients despite being older and more frail

- Improvements in PROs were seen within 3 months of treatment initiation, and were sustained or enhanced with longer treatment

- These findings further support the use of Dara-based regimens in the frontline setting regardless of transplant eligibility, age, or frailty

**In this real-world study, significant and clinically meaningful improvements in PROs were observed in TE and TIE/TD patients with NDMM treated with Dara-based regimens, consistent with the PROs observed in the clinical trials employing similar instruments**

Dara, daratumumab; NDMM, newly diagnosed multiple myeloma; PRO, patient-reported outcome; TD, transplant deferred; TE, transplant eligible; TIE, transplant ineligible.