Clinical Outcomes in Black Patients With Relapsed/Refractory Multiple Myeloma Following Talquetamab Treatment: Analyses From the Phase 1/2 MonumenTAL-1 Study

Carolina Schinke[1], Gareth Morgan[2], Luciano J Costa[3], Natalie Callander[4], Don Stevens[5], Jesus G Berdeja[6], Brea Lipe[7], Sagar Lonial[8], Marie-Christiane Vekemans[9], Ravi Vij[10], Philippe Moreau[11], Paula Rodríguez-Otero[12], Anna Sureda Balari[13], Thomas Renaud[14], Jaszianne Tolbert[15], Bonnie W Lau[15], Brandi W Hilder[15], Tara J Masterson[15], Michela Campagna[16], Veronique Vreys[17], Christoph Heuck[15], Colleen Kane[15], Kathleen S Gray[18], Deeksha Vishwamitra[15], Indrajeet Singh[15], Joy Gong[15], Xiang Qin[15], Larysa Sanchez[19]

[1]Myeloma Center, University of Arkansas for Medical Sciences, Little Rock, AR, USA; [2]New York University Langone, New York, NY, USA; [3]University of Alabama at Birmingham, Birmingham, AL, USA; [4]Carbone Cancer Center, University of Wisconsin, Madison, WI, USA; [5]Norton Cancer Institute, Louisville, KY, USA; [6]Sarah Cannon Research Institute, Tennessee Oncology, Nashville, TN, USA; [7]University of Rochester Medical Center, Rochester, NY, USA; [8]Emory University School of Medicine and Winship Cancer Institute, Atlanta, GA, USA; [9]Cliniques Universitaires Saint-Luc, Brussels, Belgium; [10]Washington University School of Medicine, St. Louis, MO, USA; [11]University Hospital Hôtel-Dieu, Nantes, France; [12]Cancer Center Clínica Universidad de Navarra, Cima, Pamplona, Spain; [13]Institut Català d'Oncologia – Hospitalet, IDIBELL, University of Barcelona, Barcelona, Spain; [14]Janssen Research & Development, Raritan, NJ, USA; [15]Janssen Research & Development, Spring House, PA, USA; [16]Janssen Research & Development, Madrid, Spain; [17]Janssen Research & Development, Beerse, Belgium; [18]Janssen Research & Development, Bridgewater, NJ, USA; [19]Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, New York, NY, USA

Presented by C Schinke at the 66th American Society of Hematology (ASH) Annual Meeting; December 7–10, 2024; San Diego, CA, USA

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Introduction

- Talquetamab is the first approved GPRC5D-targeting bispecific antibody approved for RRMM[1-3]
- In the phase 1/2 MonumenTAL-1 study, talquetamab showed ORRs of >71% and a clinically manageable safety profile in patients with RRMM[4]
- Black patients have a higher incidence of MM and higher mortality due to MM but are underrepresented in MM clinical trials[5]
- Preliminary analyses have suggested similar efficacy but higher rates of GPRC5D-related AEs with talquetamab in Black vs White patients
- We present clinical outcomes with talquetamab among Black patients from MonumenTAL-1

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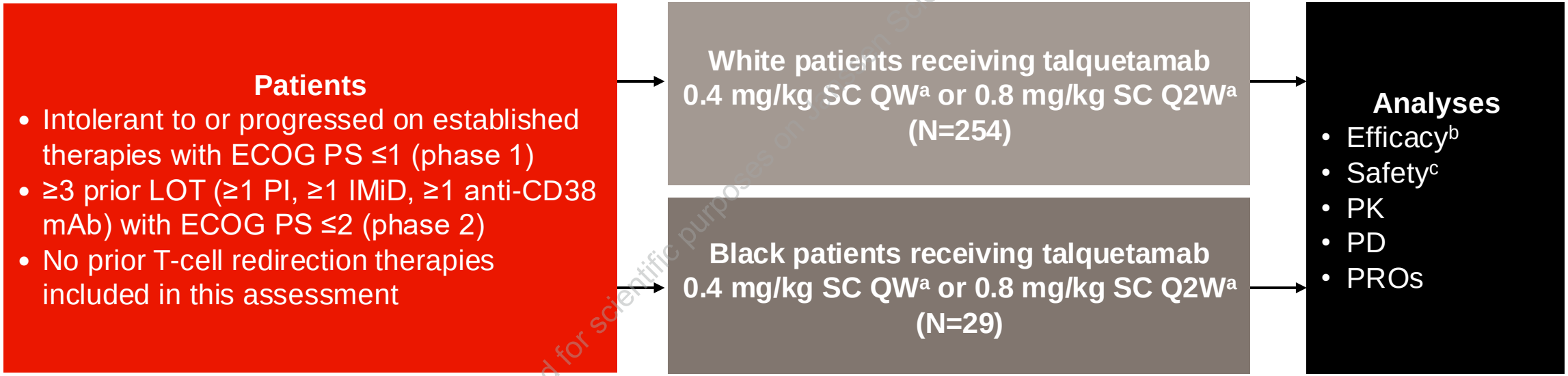
MonumenTAL-1 ClinicalTrials.gov identifier: NCT03399799/NCT04634552.
AE, adverse event; GPRC5D, G protein–coupled receptor class C group 5 member D; MM, multiple myeloma; ORR, overall response rate; RRMM, relapsed/refractory multiple myeloma.
1. Verkleij CPM, et al. *Blood Adv* 2021;5:2196-215. 2. TALVEY™ (talquetamab-tgvs). Prescribing information. Horsham, PA: Janssen Biotech, Inc.; 2023. 3. European Medicines Agency. TALVEY™ (talquetamab). Accessed October 8, 2024. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/talvey. 4. Schinke C, et al. Presented at ASCO; June 2–6, 2023; Chicago, IL, USA & Virtual. #8036. 5. Bhutani M, et al. *Blood Cancer J* 2023;13:189.

MonumenTAL-1: Assessment in Black and White Patients



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[a]With 2–3 step-up doses. [b]ORR assessed by IRC using International Myeloma Working Group criteria.[1,2] PFS based on IRC assessment. [c]CRS was graded by ASTCT criteria; all other AEs were graded by CTCAE v4.03.
AE, adverse event; ASTCT, American Society of Transplantation and Cellular Therapy; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; IRC, independent review committee; LOT, line of therapy; mAb, monoclonal antibody; ORR, overall response rate; PD, pharmacodynamics; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; PRO, patient-reported outcome; Q2W, every other week; QW, weekly; SC, subcutaneous.

1. Rajkumar SV, et al. *Blood* 2011;117:4691-5. 2. Kumar S, et al. *Lancet Oncol* 2016;17:328-46.

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MonumenTAL-1: Baseline Characteristics in Black and White Patients

Characteristic	White (N=254)	Black (N=29)
Median age, years (range)	67 (38–84)	67 (46–86)
Male, n (%)	144 (56.7)	17 (58.6)
High-risk cytogenetics,[a] n (%)	75 (32.8)	5 (22.7)
ISS stage III,[b] n (%)	56 (22.1)	6 (20.7)
Extramedullary plasmacytomas,[c] n (%)	63 (24.8)	9 (31.0)
Median prior LOT, (range)	5 (2–17)	4 (3–10)
Refractory status, n (%)		
Triple-class[d]	191 (75.2)	17 (58.6)
Penta-drug[e]	73 (28.7)	7 (24.1)

[a]del(17p), t(4;14), and/or t(14;16); percentages calculated from n=229 for White and n=22 for Black patients. [b]Calculated from n=253 for White patients. [c]Soft tissue plasmacytomas not associated with the bone were included.
[d]≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 mAb. [e]≥2 PIs, ≥2 IMiDs, and ≥1 anti–CD38 mAb.
IMiD, immunomodulatory drug; ISS, International Staging System; LOT, line of therapy; mAb, monoclonal antibody; PI, proteasome inhibitor.

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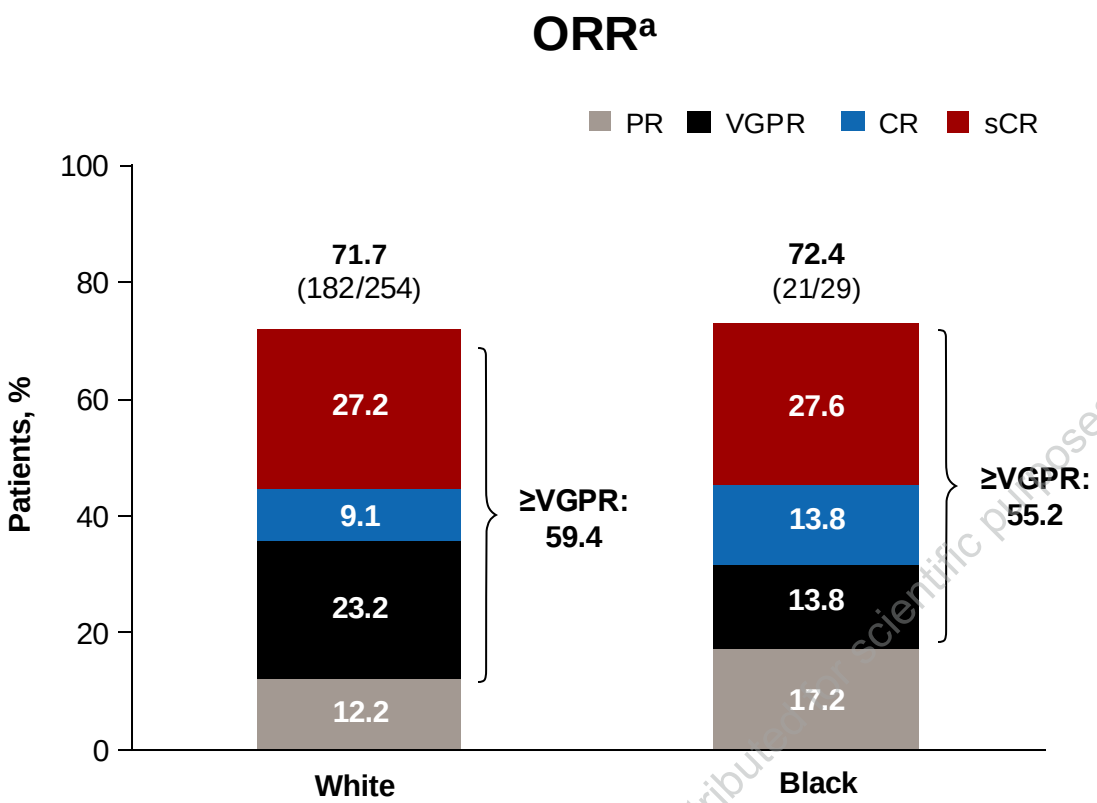
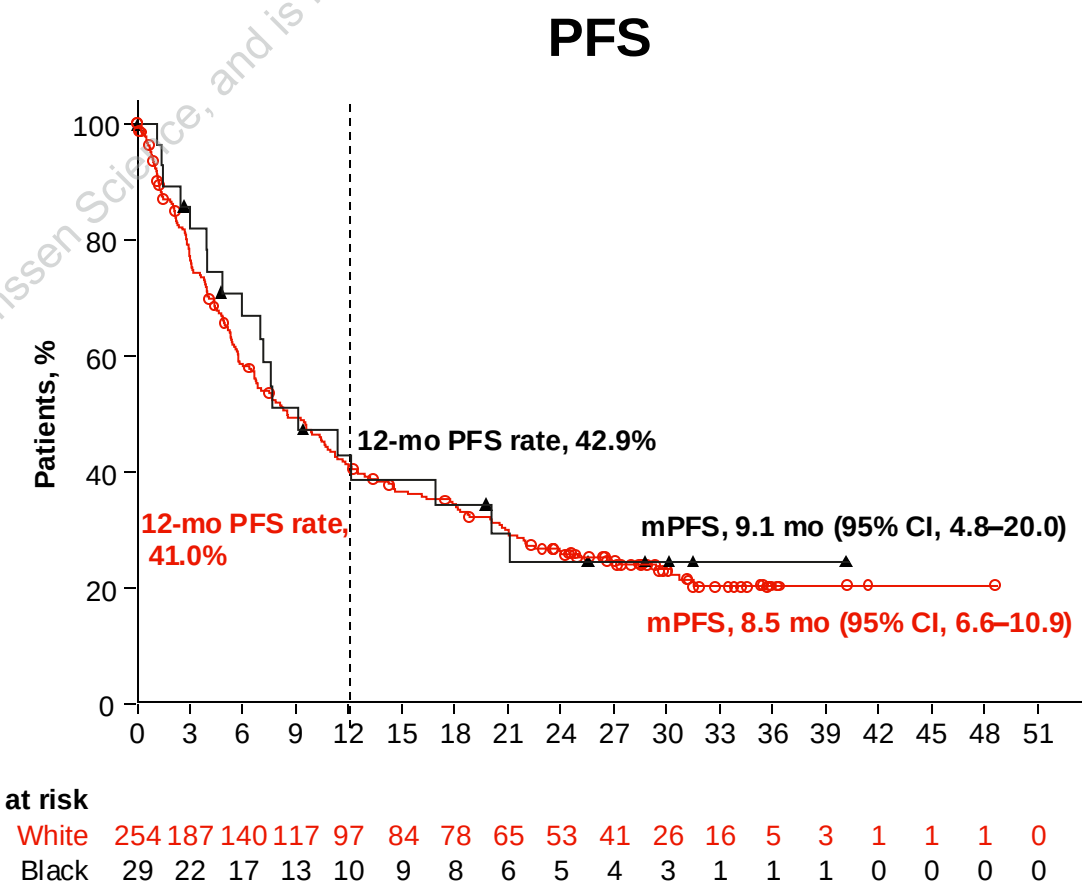
MonumenTAL-1: High ORR and Deep and Durable Responses in Black and White Patients





Median follow-up, 26 months (Black) and 31 months (White).
[a]Due to rounding, individual response rates may not sum to the ORR.
CR, complete response; mPFS, median progression-free survival; PFS, progression-free survival; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

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MonumenTAL-1: Comparable Neutropenia Rates Between Black and White Patients

AEs, n (%)	White (N=254)		Black (N=29)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Hematologic AEs (≥30% in either group)				
Anemia	119 (46.9)	75 (29.5)	9 (31.0)	7 (24.1)
Lymphopenia	67 (26.4)	59 (23.2)	11 (37.9)	11 (37.9)
Neutropenia	77 (30.3)	62 (24.4)	9 (31.0)	8 (27.6)
Thrombocytopenia	77 (30.3)	53 (20.9)	5 (17.2)	3 (10.3)

AE, adverse event.

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MonumenTAL-1: Higher Incidence of Dysgeusia and Skin-Related AEs in Black Patients

AEs, n (%)	White (N=254)		Black (N=29)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Nonhematologic AEs (≥35% in either group)				
Dysgeusia[a]	178 (70.1)	NA	26 (89.7)	NA
Skin related[b]	163 (64.2)	0	25 (86.2)	0
CRS	193 (76.0)	4 (1.6)	21 (72.4)	0
Infections	168 (66.1)	57 (22.4)	18 (62.1)	6 (20.7)
Nail related[c]	142 (55.9)	0	17 (58.6)	0
Weight decreased	100 (39.4)	10 (3.9)	15 (51.7)	2 (6.9)
Fatigue	63 (24.8)	0	12 (41.4)	0
Dry mouth	80 (31.5)	0	11 (37.9)	0
Decreased appetite	60 (23.6)	0	11 (37.9)	0
Constipation	43 (16.9)	0	11 (37.9)	0
Rash related[d]	95 (37.4)	8 (3.1)	7 (24.1)	1 (3.4)

[a]Includes dysgeusia, ageusia, taste disorder, and hypogeusia. Per CTCAE v4.03, the maximum grade of dysgeusia is 2. [b]Includes skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [c]Includes nail discoloration, nail disorder, nail toxicity, nail dystrophy, nail ridging, onychoclasis, onycholysis, and onychomadesis. [d]Includes rash, maculopapular rash, erythematous rash, and erythema.
AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable.

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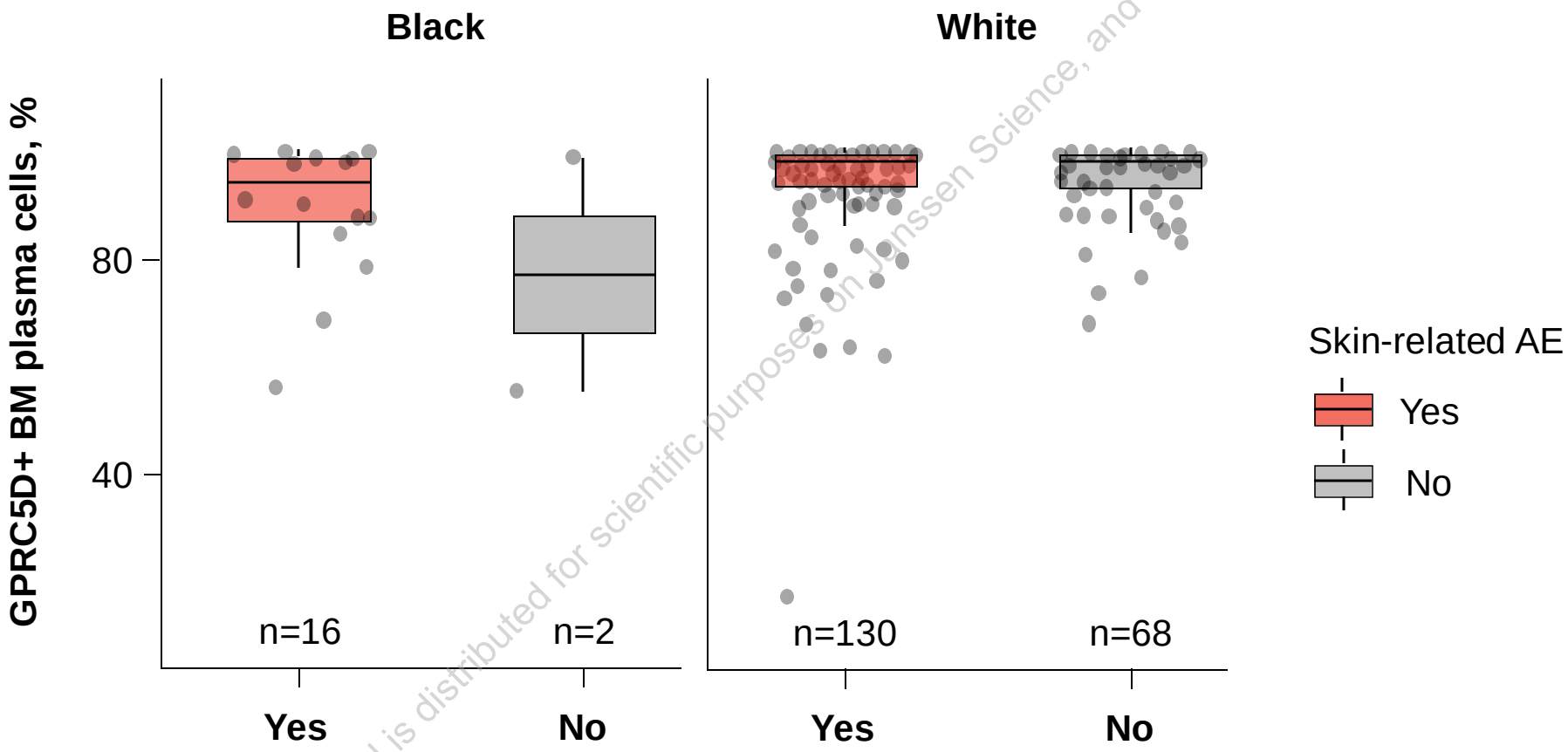
MonumenTAL-1: Higher Baseline GPRC5D Expression in Black Patients With Skin-Related AEs



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AE, adverse event; BM, bone marrow; GPRC5D, G protein–coupled receptor class C group 5 member D.

MonumenTAL-1: Greater Improvements in Many PRO Measures in Black Patients

PK/PD

- Race was not identified as a covariate impacting the PK of talquetamab
- PD analysis indicated no differences between Black and White patients

PROs

- Black patients had worse baseline values in appetite loss, constipation, dyspnea, pain, and social functioning, but reported greater improvements from baseline in these values, as well as in diarrhea (after cycle 1), fatigue, and global health status vs White patients
- With time, both Black and White patients reported improvements in disease severity; by cycle 3, most patients reported severity as “moderate,” “mild,” or “none”

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PD, pharmacodynamics; PK, pharmacokinetics; PRO, patient-reported outcome.

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Conclusions

- High ORR and deep and durable responses were observed in Black and White patients, with comparable efficacy outcomes between groups
- Differences in dysgeusia and skin-related AEs (higher incidence, longer duration, and more dose modifications needed in Black patients) require further study to better inform clinical management of Black patients treated with talquetamab
- Overall, no PK/PD differences were observed between Black and White patients; PROs indicated worse baseline scores in Black patients but greater improvements in many quality-of-life measures vs White patients

Efficacy of talquetamab was similar between Black and White patients, whereas higher rates of dysgeusia and skin-related AEs were experienced by Black patients; small numbers of Black patients warrant confirmation of these results in larger studies

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AE, adverse event; ORR, overall response rate; PD, pharmacodynamics; PK, pharmacokinetics; PRO, patient-reported outcome.

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