ELSEVIER

Blood 142 (2023) 2385–2387

The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

Patient (pt) Experiences of Receiving Idecabtagene Vicleucel (Ide-Cel, bb2121) Versus Standard (Std) Regimens for the Treatment (Tx) of Relapsed/Refractory Multiple Myeloma (RRMM) in the Randomized, Controlled KarMMa-3 Clinical Trial: Analysis of Longitudinal Qualitative Interviews

Paula Rodríguez Otero, MD[1], *Krina K. Patel, MD Msc*[2], *Noopur S. Raje*[3], *Olga Moshkovich, MPH*[4], *Heather Gerould, MS*[5], *Jennifer Devlen*[4], *Devender Dhanda, PhD*[6], *Laurie Eliason, MPH*[6], *Mark Cook, MBChB, PhD*[7], *Mihaela Popa-McKiver, MD PhD*[6], *Salomon Manier, MDPhD*[8]

[1] Clínica Universidad de Navarra, Pamplona, Spain
[2] The University of Texas MD Anderson Cancer Center, Houston, TX
[3] Massachusetts General Hospital, Boston, MA
[4] ICON Clinical Research, Raleigh, NC
[5] Formerly ICON Clinical Research, Raleigh, NC
[6] Bristol Myers Squibb, Princeton, NJ
[7] Celgene International Sàrl, a Bristol-Myers Squibb Company, Boudry, Switzerland
[8] Centre Hospitalier Universitaire de Lille, Lille, France

Introduction: Ide-cel is a first-in-class B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell therapy approved by the United States (US) Food and Drug Administration; the European Medicines Agency; and Japan's Ministry of Health, Labour, and Welfare for treating adult pts with RRMM who were triple-class exposed (TCE) to an immunomodulatory (IMiD) agent, proteasome inhibitor (PI), and anti-CD38 monoclonal antibody and who experienced disease progression/relapse after last therapy.

The phase 3 multicenter, open-label, randomized controlled KarMMa-3 trial (NCT03651128) enrolled pts with RRMM who were TCE (including an IMiD agent, PI, and daratumumab [DARA]) after 2-4 prior lines of therapy. Pts were randomized 2:1 to receive either ide-cel or 1 of 5 std regimens (DARA, pomalidomide [POM], dexamethasone [DEX]; DARA, bortezomib, DEX; ixazomib, lenalidomide, DEX; carfilzomib and DEX; elotuzumab, POM, DEX). At median follow-up (18.6 mo), median progression-free survival (13.3 vs 4.4 mo) and response rate (71% vs 42%) were significantly higher in the ide-cel versus std regimen arm (Rodriguez-Otero P, et al. *N Engl J Med* 2023;388:1002-1014). In addition to the standard pt-reported outcomes instruments, trial-embedded interviews provide further insights into the patient Tx experience (Delforge M, et al. *J Clin Oncol* 2023;41[suppl 16]. Abstract 8032).

This study assessed Tx experience, changes in health-related quality of life, and advantages and disadvantages of assigned Tx for pts enrolled in the KarMMa-3 trial.

Methods: To obtain pts' experiences and perspectives in their own words while on the assigned Tx arms during the study, qualitative interviews were embedded into the KarMMa-3 trial. Pts were randomized (1:4) to participate in a series of optional qualitative interviews conducted at baseline (BL), and 3 and 6 mo post Tx. Interviews were audio-recorded and transcribed. Non-English interviews were transcribed directly into English. Transcripts were analyzed in MAXQDA qualitative analysis software; inter-coder agreement exercises were completed to ensure reliability. Analytic approaches included thematic analysis and longitudinal analysis across aspects of health and well-being.

Results: In total, 64 pts (n = 43 ide-cel, n = 21 std regimen) across 9 countries in Europe and in the USA participated in ≥ 1 interview. Across both arms, 60, 48, and 38 pts completed interviews at BL, and 3 and 6 mo post Tx, respectively. The mean (median) age of interviewed pts at time of consent in the trial was 60.5 (60) years, and 33% were female.

When describing their overall well-being during the previous 4 weeks at 3 mo, 53% of ide-cel pts described their well-being as mostly improved versus 19% in the std regimen arm. In the ide-cel arm, 59% and 56% of pts reported improvements in physical health versus 19% and 10% of pts in the std arm at 3 and 6 mo from BL, respectively; 25% and 28% of pts in the ide-cel arm reported worsening physical health at 3 and 6 mo from BL versus 63% and 80% of pts in the std arm (Table 1). In the ide-cel arm, 47% and 48% of ide-cel pts described improvements in physical functioning at 3 and 6 mo from BL versus

19% and 20% of std regimen pts, respectively; 22% and 16% of pts in the ide-cel arm versus 50% and 60% of pts in the std arm reported worse physical functioning at 3 and 6 mo from BL.
Regarding Tx advantages, ide-cel pts reported efficacy (n = 25, 58%), minimal side effects (n = 21, 49%), avoidance of other therapies (n= 16, 37%), and having a 1-time Tx (n = 12, 28%). Std regimen pts also described efficacy (n = 10, 48%) and minimal side effects (n = 8, 38%) as Tx advantages. Disadvantages discussed by pts treated with ide-cel included lack of efficacy (n = 10, 23%), side effects after infusion (n = 9, 21%), or none (n = 9, 21%). Greater proportions of std regimen pts described side effects (n = 9, 43%) and lack of efficacy (n = 7, 33%). Additional well-being results for both arms are presented in Table 1.
Conclusions: This study provides unique insight into key pt perceptions of ide-cel Tx compared to std regimens. Overall, pts receiving ide-cel reported more positive changes 6 mo post Tx than pts receiving std regimens, specifically in physical health and functioning. Fewer pts treated with ide-cel described side effects than pts receiving std regimens. These data show that ide-cel as a 1-time infusion can alleviate the burden of managing complex medication regimens in TCE early-line relapse pts.

Disclosures Rodríguez Otero: *Amgen:* Other: Honoraria for lectures; *Regeneron:* Other: Honoraria for lectures; *AbbVie:* Consultancy, Membership on an entity's Board of Directors or advisory committees; *Oncopeptides:* Membership on an entity's Board of Directors or advisory committees; *Pfizer:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel grant; *Roche:* Consultancy; *GlaxoSmithKline:* Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Sanofi:* Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Janssen:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Bristol Myers Squibb:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures. **Patel:** *AbbVie; Allogene Therapeutics, Inc.; Arcellx; Bristol Myers Squibb/Celgene Corporation; Cellectis; Janssen Pharmaceuticals, Inc.; Nektar Therapeutic; Poseida Therapeutics; Precision BioSciences, Inc.; and Takeda Pharmaceuticals U.S.A., Inc.:* Research Funding; *Takeda:* Consultancy; *AbbVie; Arcellx, AstraZeneca; Bristol Myers Squibb/Celgene Corporation; Caribou Science; Cellectis; Curio Bioscience; Genentech; Janssen Pharmaceuticals, Inc.; Karyopharm; Legend Biotech; Merck & Co., Inc.; Oncopeptides; Pfizer; Precision BioSciences:* Consultancy. **Raje:** *Pfizer:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *AbbVie:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Immuneel:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Caribou Biosciences:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Janssen:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *K36 Therapeutics:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *GlaxoSmithKline:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Bristol Myers Squibb:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Sanofi:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding. **Moshkovich:** *Bristol Myers Squibb:* Research Funding; *ICON Clinical Research:* Current Employment. **Gerould:** *ICON plc:* Ended employment in the past 24 months. **Devlen:** *ICON plc:* Current Employment, Current equity holder in publicly-traded company. **Dhanda:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Eliason:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company; *GlaxoSmith-Kline:* Ended employment in the past 24 months. **Cook:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Popa-McKiver:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Manier:** *BMS:* Honoraria; *Amgen:* Honoraria; *Abbvie, Amgen, Celgene/BMS, GlaxoSmithKline, Janssen, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda:* Membership on an entity's Board of Directors or advisory committees; *Janssen:* Honoraria.

Table 1. Patient-reported changes in well-being from BL

	Changes from BL to 3 mo post Tx		Changes from BL to 6 mo post Tx	
	Ide-cel (n = 32)[a]	Std (n = 16)[a]	Ide-cel (n = 25)[b]	Std (n = 10)[b]
Physical health, n (%)				
Improve	19 (59)	3 (19)	14 (56)	1 (10)
Worsen	8 (25)	10 (63)	7 (28)	8 (80)
Stable/+	3 (9)	0	2 (8)	0
Stable/−	2 (6)	2 (13)	0	0
Unknown/Unclear	0	1 (6)	2 (8)	1 (10)
Physical functioning, n (%)				
Improve	15 (47)	3 (19)	12 (48)	2 (20)
Worsen	7 (22)	8 (50)	4 (16)	6 (60)
Stable/+	8 (25)	2 (13)	4 (16)	0
Stable/−	1 (3)	3 (19)	2 (8)	1 (10)
Unknown/Unclear	1 (3)	0	3 (12)	1 (10)
Social functioning, n (%)				
Improve	5 (16)	1 (6)	8 (32)	1 (10)
Worsen	3 (9)	6 (38)	3 (12)	1 (10)
Stable/+	19 (59)	5 (31)	9 (36)	4 (40)
Stable/−	2 (6)	2 (13)	1 (4)	2 (20)
Unknown/Unclear	3 (9)	2 (13)	4 (16)	2 (20)
Emotional Functioning, n (%)				
Improve	16 (50)	5 (31)	12 (48)	3 (30)
Worsen	5 (16)	9 (56)	6 (24)	5 (50)
Stable/+	7 (22)	0	4 (16)	1 (10)
Stable/−	3 (9)	1 (6)	0	0
Unknown/Unclear	1 (3)	1 (6)	3 (12)	1 (10)
Professional life, n (%)				
Improve	2 (6)	1 (6)	3 (12)	1 (10)
Worsen	7 (22)	2 (13)	4 (16)	1 (10)
Stable/+	4 (13)	2 (13)	2 (8)	0
Stable/−	6 (19)	4 (25)	3 (12)	2 (20)
Unknown/Unclear	0	1 (6)	3 (12)	2 (20)
Retired at BL	13 (41)	6 (38)	10 (40)	4 (40)
Current (4 weeks) well-being, n (%)				
Mostly improved	17 (53)	3 (19)	8 (32)	1 (10)
Mostly worsened	5 (16)	6 (38)	3 (12)	3 (30)
Stable/+	1 (3)	0	4 (16)	0
Stable/−	0	0	1 (4)	1 (10)
Fluctuating	2 (6)	1 (6)	2 (8)	1 (10)
Unknown	7 (22)	6 (38)	7 (28)	4 (40)
Current (7 days) functioning, n (%)				
Increase	11 (34)	1 (6)	10 (40)	2 (20)
Decrease	7 (22)	7 (44)	3 (12)	5 (50)
Stable/+	7 (22)	4 (25)	7 (28)	1 (10)
Stable/−	5 (16)	3 (19)	3 (12)	1 (10)
Unknown	2 (6)	1 (6)	2 (8)	1 (10)

Stable/+ refers to a patient maintaining a positive status over time without worsening, and stable/− is defined by maintaining a negative status over time without improvement. Physical health refers to how a patient feels physically. Physical functioning refers to what the patient is able to do in their daily life.
[a]Number of patients with available data at BL and 3 mo; [b]Number of patients with available data at BL and 6 mo.
BL, baseline; ide-cel, idecabtagene vicleucel; mo, month; std, standard of care; Tx, treatment.

Figure 1

https://doi.org/10.1182/blood-2023-173840