Final analysis of the phase III non-inferiority COLUMBA study of subcutaneous *versus* intravenous daratumumab in patients with relapsed or refractory multiple myeloma

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Received: June 25, 2021.
Accepted: March 23, 2022.
Prepublished: March 31, 2022.

https://doi.org/10.3324/haematol.2021.279459

Abstract

In the primary analysis of the phase III COLUMBA study, daratumumab by subcutaneous administration (DARA SC) demonstrated non-inferiority to intravenous administration (DARA IV) for relapsed or refractory multiple myeloma (RRMM). Here, we report the final analysis of efficacy and safety from COLUMBA after a median of 29.3 months follow-up (additional 21.8 months after the primary analysis). In total, 522 patients were randomized (DARA SC, n=263; DARA IV, n=259). With longer follow-up, DARA SC and DARA IV continued to show consistent efficacy and maximum trough daratumumab concentration as compared with the primary analysis. The overall response rate was 43.7% for DARA SC and 39.8% for DARA IV. The maximum mean (standard deviation [SD]) trough concentration (cycle 3, day 1 pre-dose) of serum DARA was 581 (SD, 315) µg/mL for DARA SC and 496 (SD, 231) µg/mL for DARA IV. Median progression-free survival was 5.6 months for DARA SC and 6.1 months for DARA IV; median overall survival was 28.2 months and 25.6 months, respectively. Grade 3/4 treatment-emergent adverse events occurred in 50.8% of patients in the DARA SC group and 52.7% in the DARA IV group; the most common (≥10%) were thrombocytopenia (DARA SC, 14.2%; DARA IV, 13.6%), anemia (13.8%; 15.1%), and neutropenia (13.1%; 7.8%). The safety profile remained consistent with the primary analysis after longer follow-up. In summary, DARA SC and DARA IV continue to demonstrate similar efficacy and safety, with a low rate of infusion-related reactions (12.7% *vs.* 34.5%, respect-

ively) and shorter administration time (3-5 minutes *vs.* 3-7 hours) supporting DARA SC as a preferable therapeutic choice. (Clinicaltrials gov. Identifier: NCT03277105.

Introduction

Daratumumab is a human immunoglobulin Gκ monoclonal antibody targeting CD38 with a direct on-tumor[1-4] and immunomodulatory[5-7] mechanism of action. Daratumumab by intravenous administration (DARA IV) is approved for use in many countries for the treatment of relapsed or refractory multiple myeloma (RRMM) as a monotherapy or combined with standard of care for RRMM or for newly diagnosed multiple myeloma.[8,9]

A subcutaneous formulation of daratumumab (DARA SC; daratumumab 1,800 mg co-formulated with recombinant human hyaluronidase PH20 [rHuPH20; 2,000 U/mL; ENHANZE® drug delivery technology; Halozyme, Inc., San Diego, CA, USA]) was developed to reduce the duration of treatment administration (3-5 minutes for DARA SC *vs.* 3-7 hours for DARA IV) without compromising efficacy and safety. Based on the previously published primary analysis of the COLUMBA study,[10] DARA SC was approved for use in the United States, European Union, and other countries globally as monotherapy for RRMM and combination therapy for RRMM or newly diagnosed multiple myeloma.[9,11]

The primary analysis of the phase III COLUMBA study demonstrated that DARA SC was non-inferior to DARA IV in terms of the co-primary endpoints of efficacy (overall response rate [ORR]) and pharmacokinetics (maximum trough concentration measured pre-dose cycle 3, day 1 [C_{trough}]). With a median follow-up time of 7.5 months, the ORR for DARA SC and DARA IV was 41% and 37%, respectively (relative risk 1.11: 95% confidence interval [CI]: 0.89-1.37). Maximum C_{trough} was chosen as a co-primary endpoint because this parameter was strongly correlated with efficacy.[12] The maximum C_{trough} in the DARA SC group was 593 (standard deviation [SD], 306) µg/mL and in the DARA IV group was 522 (SD, 226) µg/mL; the geometric means ratio was 107.93% (90% CI: 95.74-121.67). DARA SC was well tolerated with a safety profile comparable to that of DARA IV, and DARA SC had a lower rate of infusion-related reactions (IRR) compared with DARA IV (13% *vs.* 34%; $P<0.0001$).[10] Herein, we report the final analysis of the COLUMBA study, with a longer follow-up of 29.3 months (an additional 21.8 months after the primary analysis).

Methods

Study design and participants

The study design, including complete eligibility criteria, of the multi-center, open-label, non-inferiority, randomized phase III COLUMBA study (clinicaltrials gov. Identifier: NCT03277105) has been previously published with the prespecified co-primary endpoint analysis.[10] Briefly, COLUMBA evaluated DARA SC or DARA IV in patients with RRMM. Patients had RRMM with a multiple myeloma diagnosis according to International Myeloma Working Group criteria,[13] had received ≥3 previous lines of therapy including a proteasome inhibitor and an immunomodulatory drug, or were refractory to both a proteasome inhibitor and an immunomodulatory drug. All patients provided written informed consent. The study was approved by independent ethics committees/institutional review boards and was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practices guidelines.

Randomization and study treatment

Eligible patients were randomly assigned in a 1:1 ratio to receive either DARA SC or DARA IV, stratified by baseline body weight (≤65 kg, 66-85 kg, >85 kg), previous lines of therapy(≤4 or >4), and myeloma type (immunoglobulin G *vs.* non–immunoglobulin G). Treatment groups were not masked to patients or investigators. Patients in the DARA SC group received a flat dose of 1,800 mg of daratumumab co-formulated with rHuPH20 at 2,000 U/mL, and patients in the DARA IV group received 16 mg/kg of daratumumab. Patients received daratumumab once weekly for cycles 1-2, once every 2 weeks for cycles 3-6 (all cycles, 28 days), and then once every 4 weeks thereafter until disease progression or toxicity.

Endpoints and analyses

The non-inferiority co-primary endpoints of the COLUMBA trial were overall response and the maximum C_{trough}. Major secondary endpoints were tested sequentially in the following order: rate of IRR, progression-free survival (PFS), rate of very good partial response or better (≥VGPR), and overall survival (OS). Additional endpoints included rate of complete response or better (≥CR), time to next therapy, median PFS on the next line of therapy (PFS2; defined by time from randomization until disease progression or death on the next line of therapy), duration of response, and time to response. Disease assessments were conducted every 28 (±7) days until disease progression in accordance with International Myeloma Working Group response criteria[14] and a validated computer algorithm. The primary and final analyses occurred approximately 6 and 22 months, respectively, after the last patient was randomized.

Results

Patients and treatment

In total, 522 patients were randomized (DARA SC, n=263; DARA IV, n=259). Baseline and disease characteristics were generally well balanced and previously published.[10] At the time of the final analysis, among patients who received ≥1 treatment dose, a similar percentage in each group discontinued study treatment (DARA SC, 90.0% [n=234]; DARA IV, 91.1% [n=235]). Consistent with the primary analysis, progressive disease (75.4% [n=196]; 75.6% [n=195]) was the most common reason for treatment discontinuation in both groups. At the time of the clinical cutoff for the final analysis, 26 (10%) patients in the DARA SC group and 23 (8.9%) in the DARA IV group remained on study treatment. The median numbers of treatment cycles received were comparable for the DARA SC and DARA IV groups (7.0 [range, 1-38] and 7.5 [range, 1-37], respectively). The median daratumumab relative dose intensities were similar for the DARA SC group at 100.0% (range, 25.0-100.0) and for the DARA IV group at 99.9% (range, 1.3-106.2), with a median duration of treatment of 5.6 months (range, 0.03-34.6) and 6.1 months (range, 0.03-33.4), respectively.

Efficacy

Efficacy results at the final analysis were generally consistent with those at the primary analysis. The ORR continued to improve in both treatment groups, from 41.1% to 43.7% in the DARA SC group and from 37.1% to 39.8% in the DARA IV group. In comparison to the primary analysis, the depth of response continued to deepen over time, as shown with rates of ≥VGPR based on the computerized algorithm increasing from 19% to 23.6% for the DARA SC group and from 17% to 21.6% for the DARA IV group (odds ratio, 1.13; 95% CI: 0.74-1.72; Figure 1) and the rates of ≥CR increasing from 1.9% to 4.6% for the DARA SC group and 2.7% to 5.4% for the DARA IV group. Median time to ≥VGPR was consistent with the primary analysis (DARA SC: 2.0 months [range, 1.0-19.4]; DARA IV: 1.9 months [range, 0.9-22.8]). Responses for DARA SC were generally similar across patients in each body weight subgroup (≤65 kg, >65-85 kg, and >85 kg; *Online Supplementary Table S2*). The median time to ≥CR increased from 4.2 to 9.3 months for the DARA SC group, and from 3.8 to 7.2 months for the DARA IV group. The median duration of response was similar in both groups: 10.2 (range, 9.2-13.8) months for the DARA SC group and 10.6 (range, 9.2-15.6) months for the DARA IV group.

With a median follow-up of 29.3 months, the median PFS was consistent with the primary analysis in both treatment groups, with 5.6 (95% CI: 4.7-7.5) months and 6.1 (95% CI: 4.7-7.5) months for the DARA SC and DARA IV groups, respectively (hazard ratio [HR], 0.98; 95% CI: 0.81-1.19; Figure 2). The median OS was similar in both arms with 28.2 (95% CI: 22.8-not evaluable) months for the DARA SC group and 25.6 (95% CI: 22.1-not evaluable) months for the DARA IV group, (HR, 0.92; 95% CI: 0.72-1.18). The estimated 24-month OS rates were 55.8% (95% CI: 49.4-61.7) for DARA SC and 51.6% (95% CI: 45.1-57.6)

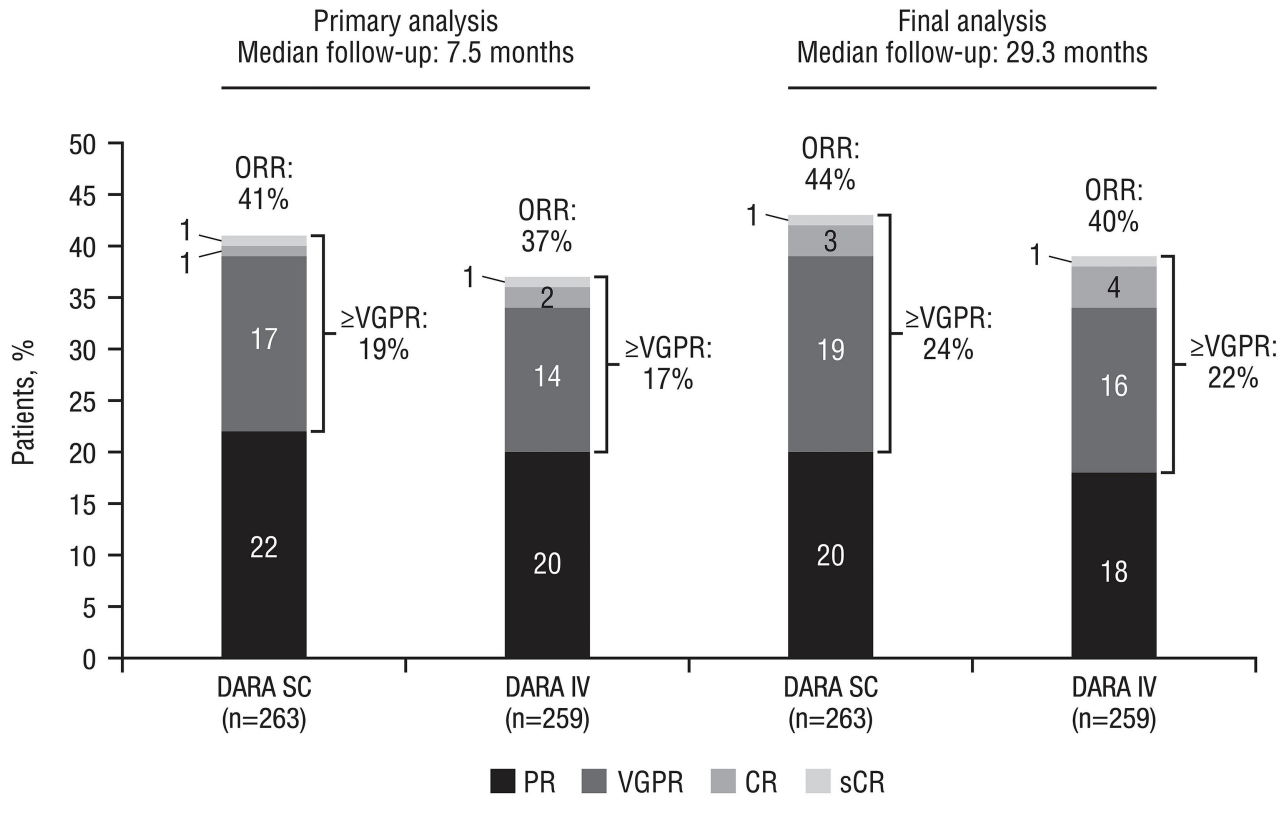

Figure 1. Response rates over time. Response rates from the primary COLUMBA analysis[10] (median follow-up, 7.5 months) and the final COLUMBA analysis (median follow-up, 29.3 months) for patients in the intent-to-treat population. Response rates are shown for the DARA SC and DARA IV groups. ORR: overall response rate; VGPR: very good partial response; PR: partial response; DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration; CR: complete response; sCR: stringent complete response.

for DARA IV (Figure 3). Median OS outcomes were generally similar for the DARA SC and DARA IV groups across baseline body weight subgroups (≤65 kg, >65-85 kg, and >85 kg; *Online Supplementary Table S2*).

The median times to next therapy were similar, with 8.8 (95% CI: 7.6-10.9) months for the DARA SC group and 9.4 (95% CI: 8.2-10.7) months for the DARA IV group (HR, 0.99; 95% CI: 0.81-1.21). PFS2 also remained similar with 19.0 (95% CI: 16.6-21.7) months for the DARA SC group and 18.1 (95% CI: 15.1-21.0) months for the DARA IV group (HR, 0.87; 95% CI: 0.70-1.10; Figure 4). The estimated 24-month PFS2 rates were 42.1% (95% CI: 35.8-48.4) and 37.1% (95% CI: 30.9-43.4) for the DARA SC and DARA IV groups, respectively.

Pharmacokinetics and immunogenicity

The final pharmacokinetic and immunogenicity results are consistent with those of the primary analysis.[10] Among patients in the pharmacokinetic analysis set (DARA SC, n=259; DARA IV, n=257), serum trough concentrations of daratumumab following treatment with DARA SC were consistently higher or comparable with those from the DARA IV group for all visits at which concentrations were measured in both treatment groups (Figure 5). Following weekly dosing, trough serum concentrations of daratumumab increased to the maximum C_{trough}, which occurred immediately prior to dosing on cycle 3 day 1 for both treatment groups. The mean maximum C_{trough} concentration was 581 (SD, 315) µg/mL for the DARA SC group and 496 (SD, 231) µg/mL for the DARA IV group. As expected for a monoclonal antibody administered SC as a flat dose and consistent with results in the primary analysis,[10] higher serum daratumumab concentrations were observed in patients with lower body weight (≤65 kg) and lower serum daratumumab concentrations were observed in patients with higher body weight (>85 kg), compared with exposures in the total pharmacokinetic analysis set in the DARA SC group. For patients treated with DARA IV, lower serum daratumumab concentrations were observed in patients with lower body weight (≤65 kg) and higher serum daratumumab concentrations were observed in patients with higher body weight (>85 kg), compared with exposures in the total pharmacokinetic analysis set (*Online Supplementary Table S1*).

Two methods were used for detection of anti-daratumumab antibodies for the final analysis: initial drug tolerance (DT) method and enhanced DT method. The enhanced DT method was developed to detect anti-daratumumab antibodies in the presence of a high concentration of daratumumab (4,000 µg/mL *vs.* 630 µg/mL in the initial DT assay). After the enhanced DT method became available, all samples were tested using the new enhanced DT

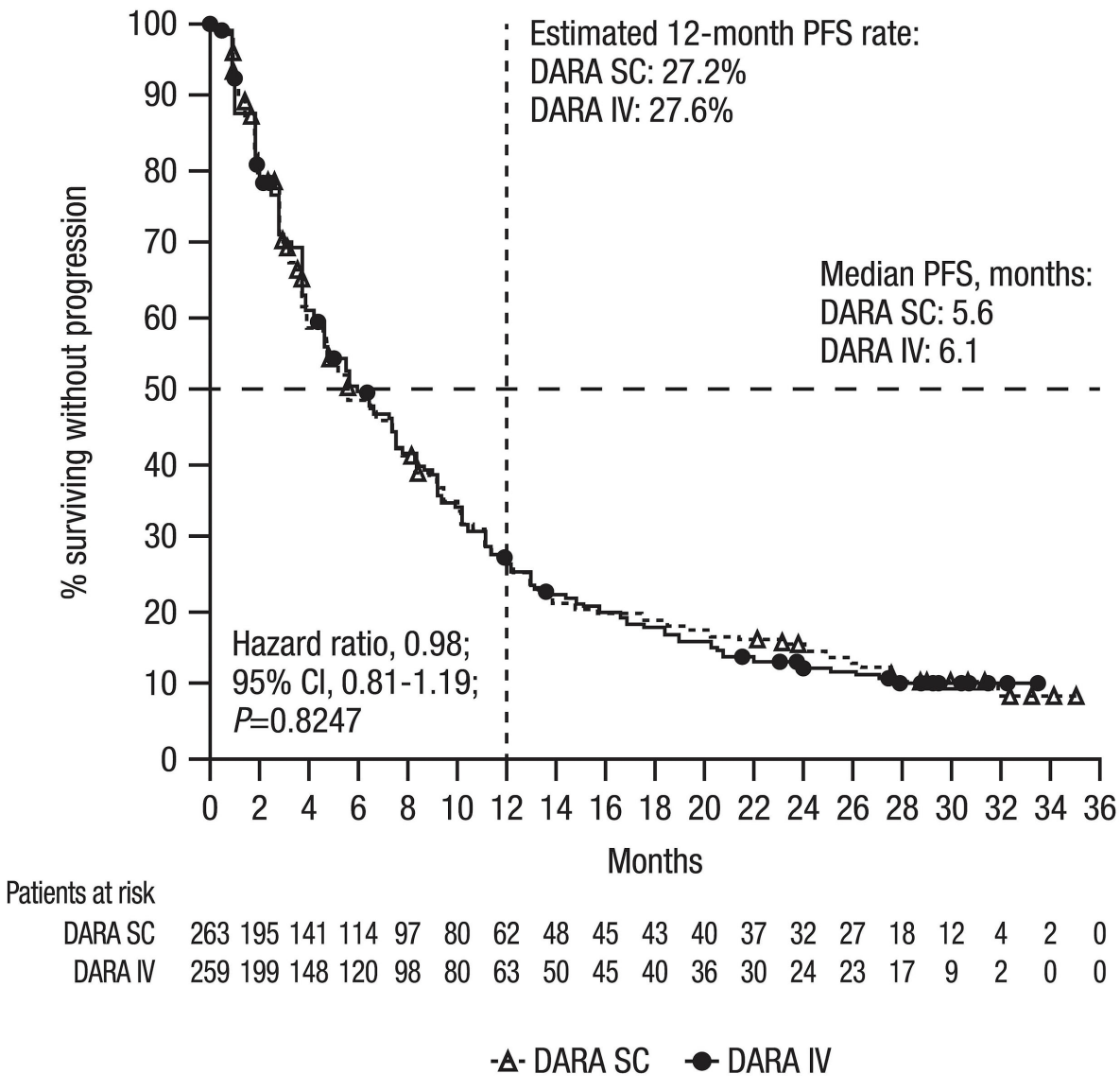

Figure 2. Kaplan-Meier estimates for progression-free survival in the intent-to-treat population. Data included all patients who underwent randomization. Estimated 12-month progression-free survival (PFS) rates are shown. DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration; CI: confidence interval.

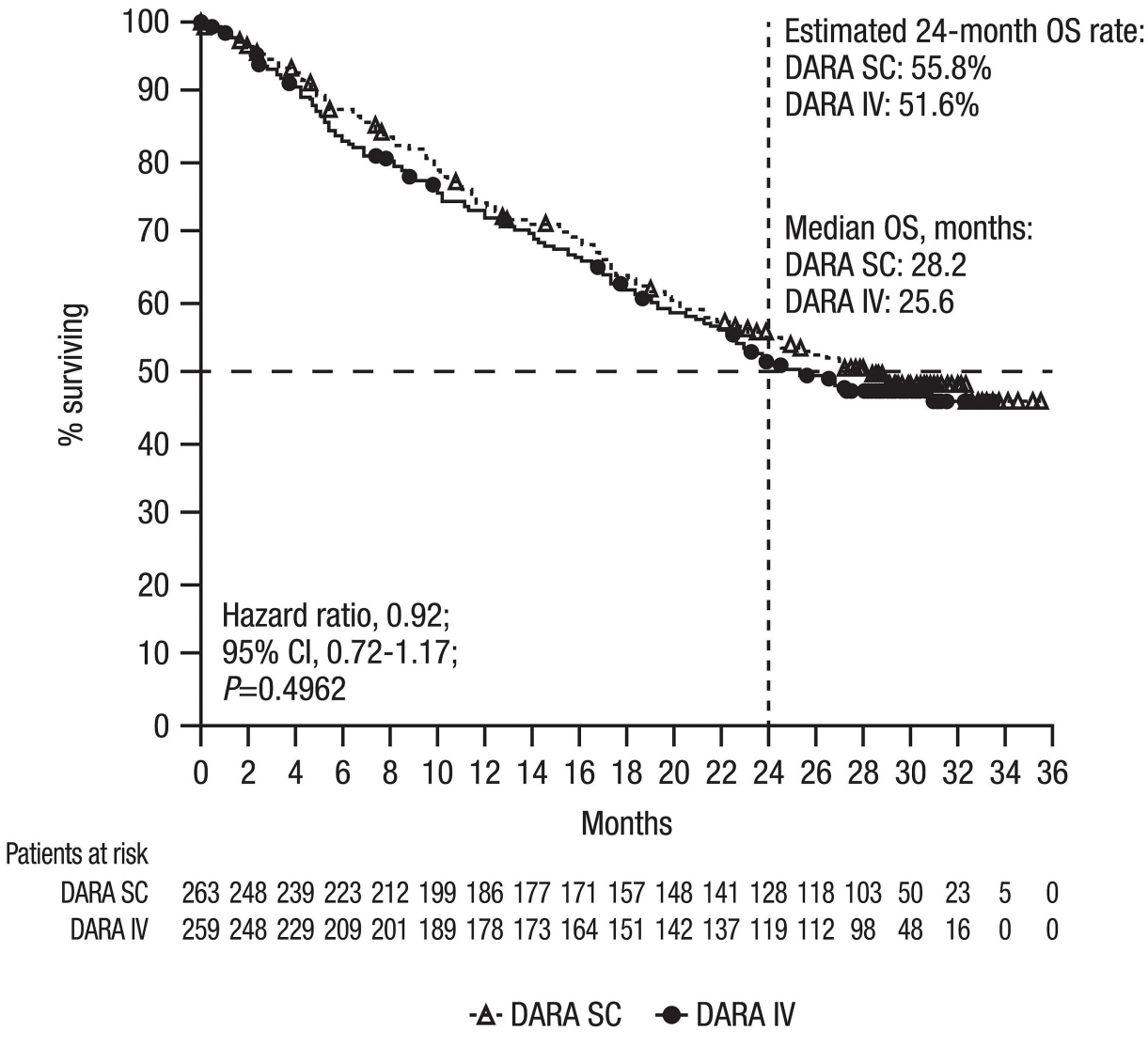

Figure 3. Kaplan-Meier estimates for overall survival in the intent-to-treat population. Data included all patients who underwent randomization. Estimated 24-month overall survival (OS) rates are shown. DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration; CI: confidence interval.

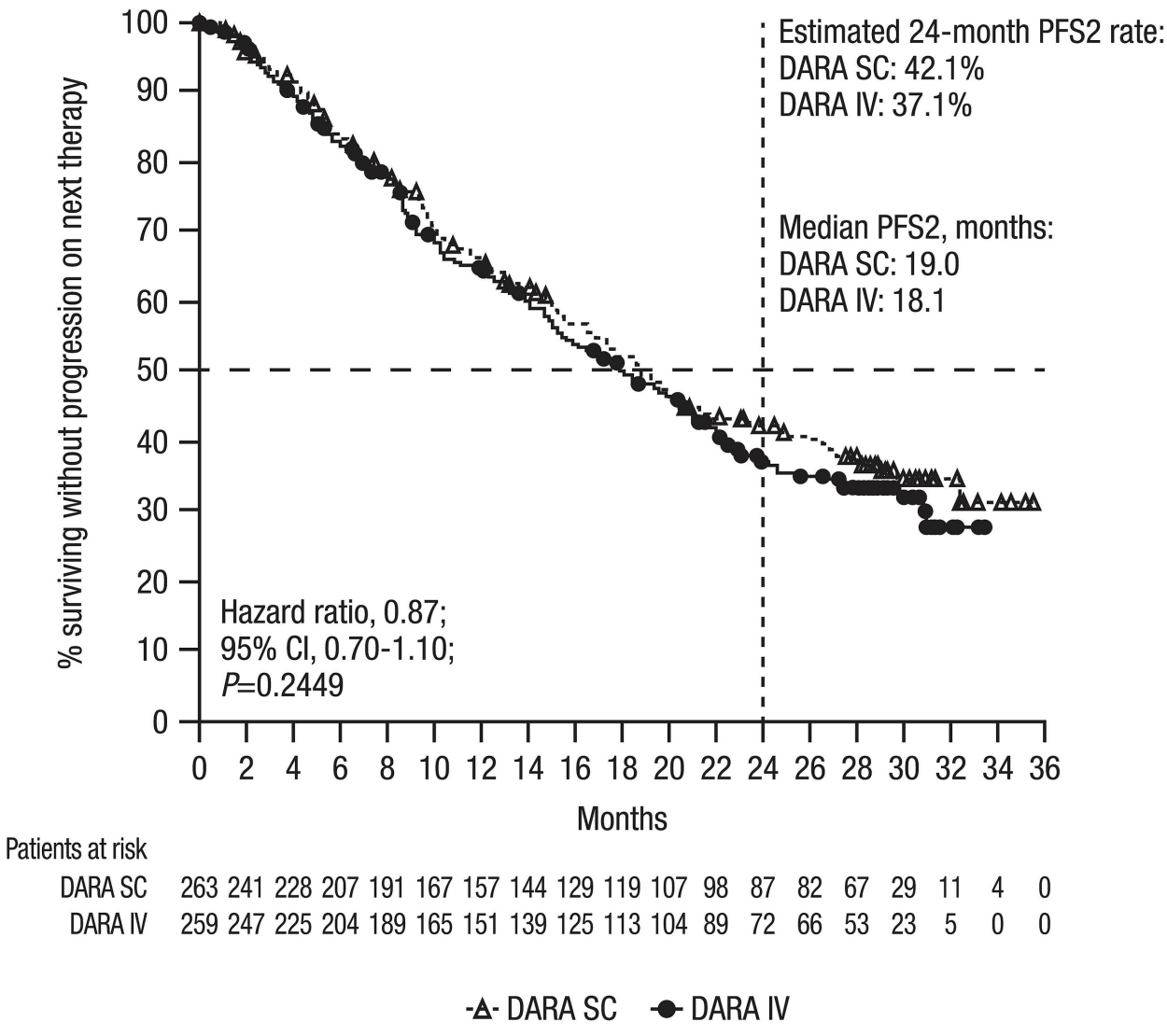

Figure 4. Kaplan-Meier estimates for progression-free survival in the intent-to-treat population. Data included all patients who underwent randomization. PFS2: time from randomization to progression on next line of therapy or death, based on investigator assessment; DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration; CI: confidence interval.

method (including samples that had been previously tested with the initial DT method during the primary analysis). Based on cumulative incidence in the daratumumab-immunogenicity-evaluable analysis set (n=228 for both DARA SC and DARA IV) of anti-daratumumab antibodies (i.e., patients positive for anti-daratumumab antibodies in either initial DT method or enhanced DT method), one (0.4%) patient tested positive for anti-daratumumab antibodies in the DARA SC group compared with six (2.6%) patients in the DARA IV group. The peak titer (based on enhanced DT method) was 1:192 in one patient who tested positive for treatment-emergent anti-daratumumab antibodies in the DARA SC group. For the six patients who tested positive for treatment-emergent anti-daratumumab antibodies in the DARA IV group, the peak titer was 1:6 in three patients, 1:24 in one patient, and 1:192 in one patient based on the enhanced DT method, and 1:20 in one patient based on the initial DT method. The one patient in the DARA SC group who tested positive for anti-daratumumab antibodies also tested positive for neutralizing antibodies, and five of six patients in the DARA IV group who tested positive for anti-daratumumab antibodies also tested positive for neutralizing antibodies.

Based on the updated rHuPH20 immunogenicity evaluable analysis set (including the primary and final analysis), 15 (6.7%) of 224 patients in the rHuPH20 immunogenicity-evaluable analysis set had treatment-emergent anti-rHuPH20 antibodies post DARA SC administration. For patients who tested positive for treatment-emergent anti-rHuPH20 antibodies, the peak titer was 1:5 in ten patients, 1:10 in three patients, and 1:80 in two patients. None of the 15 patients with treatment-emergent anti-rHuPH20 antibodies tested positive for neutralizing antibodies to rHuPH20.

Safety

The overall safety profiles of the DARA SC and DARA IV groups were similar and consistent with the primary analysis after longer follow-up, with 91.5% (n=238) and 93.0% (n=240) patients, respectively, experiencing treatment-emergent adverse events (TEAE) of any grade and the most common (>15%) in both groups being anemia, thrombocytopenia, and pyrexia (Table 1). The incidence of grade 3 or 4 TEAE for both groups was similar to the data previously reported in the primary analysis, with the final analysis reporting 50.8% (n=132) of patients in the DARA SC group and

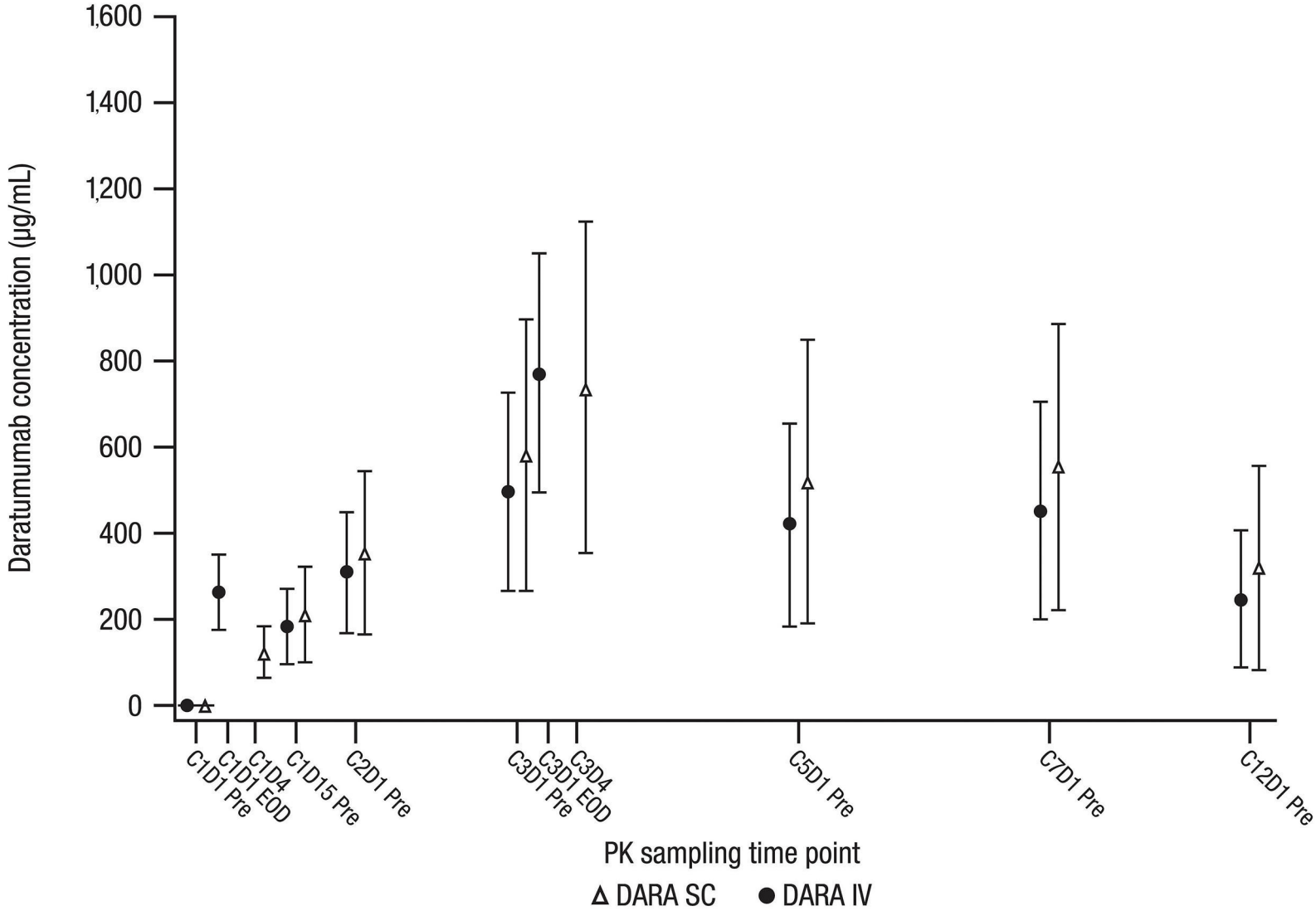

Figure 5. Plot of mean (standard deviation) daratumumab serum peak and trough concentrations over time. Data represented as mean with error bars denoting standard deviation for patients who received ≥1 administration of study therapy and had ≥1 pharmacokinetics sample concentration value after the first dose administration. C: cycle; D: day; Pre: pre-dose; EOD: end of dose; PK: pharmacokinetics; DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration.

52.7% (n=136) of patients in the DARA IV group; the most common (≥10%) were thrombocytopenia, anemia, and neutropenia (Table 1). The overall incidence of serious TEAE for both treatment groups also remained consistent with data previously reported in the primary analysis, with the final analysis reporting 31.9% (n=83) of patients in the DARA SC group and 34.5% (n=89) of patients in the DARA IV group; the most common SAE being pneumonia (4.6% [n=12]; 5.0% [n=13]). Second primary malignancies occurred at a low rate of 3.8% (n=10) of patients in the DARA SC group and 3.9% (n=10) patients in the DARA IV group.

TEAE led to treatment discontinuation in 7.3% (n=19) patients in the DARA SC group and 8.5% (n=22) patients in the DARA IV group. TEAE resulting in death occurred in 6.2% (n=16) patients in the DARA SC group and 7.4% (n=19) patients in the DARA IV group. Treatment modifications due to any grade TEAE occurred in 30.0% (n=78) of DARA SC and 32.6% (n=84) of DARA IV patients.

There was no clinically meaningful difference in the overall tolerability and safety profiles between DARA SC and DARA IV in the ≤65 kg subgroup. Patients in each body weight subgroup (≤65 kg, >65-85 kg, and >85 kg) experienced any grade and grade 3/4 TEAE at frequencies similar to those of the overall population (*Online Supplementary Table S3*). Consistent with data previously reported in the primary analysis, a higher incidence of neutropenia in the ≤65 kg subgroup in the DARA SC group compared with the DARA IV group was reported, including neutropenia of all grades (DARA SC, 25.8%; DARA IV, 14.1%) and grade 3/4 neutropenia (DARA SC, 20.4%; DARA IV, 8.7%) *(Online Supplementary Table S3*). In the ≤65 kg DARA SC subgroup there was no increase in the overall incidence of infections (DARA SC, 57.0%; DARA IV, 57.6%), grade 3 or 4 infections (10.8% and 17.4%, respectively), or serious infections (10.8% and 18.5%, respectively).

With longer follow-up, no new IRR occurred, and the rate

Table 1. Adverse event incidence and most common adverse events of any grade (≥10%) and grade 3/4 (≥5%) in the safety-evaluable population.[a]

	DARA SC (N=260)		DARA IV (N=258)	
Any TEAE, N (%)	238 (91.5)		240 (93.0)	
Serious TEAE, N (%)	83 (31.9)		89 (34.5)	
Maximum toxicity grades of TEAE, N (%)				
Grade 1	13 (5.0)		19 (7.4)	
Grade 2	92 (35.4)		85 (32.9)	
Grade 3	93 (35.8)		88 (34.1)	
Grade 4	24 (9.2)		29 (11.2)	
Grade 5	16 (6.2)		19 (7.4)	
TEAE leading to treatment discontinuation, N (%)	19 (7.3)		22 (8.5)	
TEAE resulting in death, N (%)	16 (6.2)		19 (7.4)	
TEAE, N (%)	**Any grade**	**Grade 3/4**	**Any grade**	**Grade 3/4**
Hematologic				
Anemia	72 (27.7)	36 (13.8)	66 (25.6)	39 (15.1)
Neutropenia	52 (20.0)	34 (13.1)	35 (13.6)	20 (7.8)
Thrombocytopenia	51 (19.6)	37 (14.2)	50 (19.4)	35 (13.6)
Lymphopenia	21 (8.1)	14 (5.4)	17 (6.6)	16 (6.2)
Non-hematologic				
Upper respiratory infection	44 (16.9)	0	30 (11.6)	2 (0.8)
Diarrhea	41 (15.8)	2 (0.8)	33 (12.8)	1 (0.4)
Pyrexia	39 (15.0)	2 (0.8)	39 (15.1)	2 (0.8)
Fatigue	33 (12.7)	3 (1.2)	28 (10.9)	3 (1.2)
Arthralgia	33 (12.7)	1 (0.4)	18 (7.0)	0
Back pain	31 (11.9)	5 (1.9)	38 (14.7)	7 (2.7)
Nasopharyngitis	28 (10.8)	1 (0.4)	21 (8.1)	0
Cough	25 (9.6)	2 (0.8)	36 (14.0)	0
Nausea	24 (9.2)	0	32 (12.4)	2 (0.8)
Hypertension	16 (6.2)	11 (4.2)	23 (8.9)	15 (5.8)
Pneumonia	16 (6.2)	13 (5.0)	19 (7.4)	13 (5.0)
Chills	15 (5.8)	1 (0.4)	32 (12.4)	2 (0.8)
Dyspnea	15 (5.8)	2 (0.8)	28 (10.9)	2 (0.8)
IRRs	33 (12.7)	4 (1.5)[b]	89 (34.5)	14 (5.4)[b]

DARA SC: daratumumab by subcutaneous administration; DARA IV: daratumumab by intravenous administration; TEAE: treatment-emergent adverse event; IRR: infusion-related reactions. [a]The safety-evaluable population includes all patients who underwent randomization and received ≥1 dose of study treatment. [b]No grade 4 IRR were reported for either DARA SC or DARA IV.

of IRR remained significantly reduced with DARA SC compared to DARA IV (12.7% [n=33] *vs.* 34.5% [n=89]; odds ratio, 0.28; 95% CI: 0.18-0.44; *P*<0.0001). For patients in the DARA SC group, one injection-site reaction occurred with longer follow-up. Among patients who switched from DARA IV to DARA SC (n = 13), none experienced IRR with DARA SC.

The results from the modified-Cancer Therapy Satisfaction Questionnaire (CTSQ) at the time of the final analysis confirmed, that with the longer follow-up, patients receiving DARA SC continued to have a more positive perception of their cancer therapy and greater satisfaction with therapy compared with patients receiving DARA IV (*Online Supplementary Table S3*).

Discussion

In this final analysis of the non-inferiority phase III COLUMBA study, with 29.3 months of median follow-up (approximately 22 months after the primary analysis), DARA SC and DARA IV continued to demonstrate similar efficacy and trough daratumumab concentrations, as measured by co-primary endpoints ORR and maximum C_{trough}, and supported by depth and duration of response, PFS, and OS. With longer follow-up, no new safety concerns were identified, and DARA SC maintained a lower rate of IRR *versus* DARA IV. Together, these data are consistent with the primary analysis of COLUMBA.[10]

The results from the final analysis of COLUMBA are consistent with those seen for GEN501 and SIRIUS, which were two early-phase open-label studies that established the efficacy and safety of DARA IV monotherapy in RRMM patients.[15,16] In a pooled, *post hoc* final analysis of GEN501 and SIRIUS, the combined ORR rate was 30.4%, median PFS was 4.0 months, and median OS was 20.5 months, with a combined median follow-up of 36.6 months.[17] These data are similar to the final COLUMBA analysis: ORR rates were 43.7% and 39.8%, median PFS values were 5.6 months and 6.1 months, and median OS values were 28.2 months and 25.6 months for DARA SC and DARA IV, respectively.

Pharmacokinetic analyses demonstrate that serum trough concentrations of daratumumab following treatment with DARA SC were consistently higher than or comparable with those from the DARA IV group, including the mean maximum C_{trough} concentration (DARA SC, 581 µg/mL; DARA IV, 496 µg/mL); these values exceed the previously identified threshold (236 µg/mL) established for DARA IV to reach 99% target saturation for clinical effect.[12] Analyses of pharmacokinetics by body weight subgroup were consistent with body weight analyses from the primary COLUMBA analysis.[18] Of note, there were only a small number of patients with body weight >120 kg who were treated with DARA SC in COLUMBA; therefore, the data should be interpreted with caution. Overall, DARA SC (1,800 mg) achieved adequate and consistent exposure across body weight subgroups (≤65 kg, 66-85 kg, and >85-120 kg), suggesting that dose adjustments are not required for DARA SC.

With longer follow-up at the final COLUMBA analysis (median follow-up, 29.3 months), no new safety concerns were noted. There was no clinically meaningful difference in the overall tolerability and safety between DARA SC and DARA IV in the ≤65 kg subgroup. While a higher incidence of neutropenia in the ≤65 kg subgroup in the DARA SC group was reported, it did not result in an increased rate of any grade or grade 3 or 4 infections. These findings are consistent with those of the primary analysis.

Overall, DARA SC was shown to be non-inferior to DARA IV through the primary analysis,[10] a finding that was supported with an extended follow-up. In addition, DARA SC provides several advantages compared with DARA IV. DARA SC reduces the treatment burden for patients because of its considerably shorter duration of administration, while it confers a more positive perception and greater patient satisfaction with treatment compared with DARA IV.[19] The final analysis of COLUMBA provides long-term efficacy and tolerability data on daratumumab monotherapy and strongly supports the use of DARA SC to achieve clinical outcomes comparable to those with DARA IV, with a low rate of IRR, short administration time, and without dose adjustment. Based on these results, DARA SC is considered a preferable treatment option relative to DARA IV for the patients with multiple myeloma.

Disclosures

SZU has received grants and personal fees from Amgen, Celgene, GlaxoSmithKline (GSK), Janssen, Merck, Sanofi, Seattle Genetics, SkylineDX, and Takeda; personal fees from Abbvie and MundiPharma; and grants from Bristol Myers Squibb (BMS) and Pharmacyclics. VV has received honoraria for lectures and advisory boards from Janssen, BMS, Celgene, Amgen, Takeda, AbbVie, Roche, and AstraZeneca. IS has received honoraria and consulting and lecture fees from Celgene, Amgen, Janssen-Cilag, Takeda, and Novartis; consulting and lecture fees from Sanofi; and lecture fees from BMS. VH has received fees for lectures and advisory boards from AbbVie, Amgen, BMS, Janssen, Sanofi, and Takeda. NB has received honoraria from and served as a consultant for AbbVie, Amgen, BMS, Celgene, Genentech, GSK, Janssen, Karyopharm, Sanofi, and Takeda; and received researching funding from Celgene. JB has received personal fees from Janssen, Celgene, and Amgen. PM served as consultant for and received honoraria from Janssen, Celgene/BMS, Amgen, Sanofi, and AbbVie; and received honoraria from Novartis and Takeda. AC served as a consultant for Janssen, Celgene, Novartis, Amgen, BMS,

Karyopharm, Sanofi, Genzyme, Seattle Genetics, Oncopeptides, Millennium/Takeda, Antengene, GSK, and Secura Bio; and received research funding from Janssen, Celgene, Novartis, Amgen, Pharmacyclics, Seattle Genetics, and Millennium/Takeda. MK has consulted for AbbVie, Amgen, BMS/Celgene, GSK, Janssen, Karyopharm, Seattle Genetics, and Takeda; received honoraria from BMS/Celgene, Janssen, and Takeda; received research funding from Janssen and BMS/Celgene; and travel support from BMS/Celgene, Janssen, and Takeda. SI has received honoraria and reserch grants from Celgene, Daiichi-Sankyo, Janssen, Ono, Sanofi, and Takeda; and also received research grants from AbbVie, BMS, Chugai, GSK, and Kyowa Kirin. MC has received honoraria from AbbVie, GSK, BMS, Adaptive Biotechnologies, Takeda, Janssen, and Celgene. CHul has received honoraria from Celgene/BMS, GSK, Janssen Pharmaceuticals, and Takeda. DW has received honoraria from Amgen, Antengene, BMS/Celgene, GSK, Janssen, Karyopharm, Sanofi, and Takeda. VDS reports grants, personal fees, and non-financial support from Amgen, Celgene, and Novartis. KL is an employee of and owns equity in Janssen Research & Development, LLC . LO is an employee of and owns equity in Janssen Research & Development, LLC. CHeu is an employee of and owns equity in Janssen Research & Development, LLC. MD was an employee of Janssen Research & Development, LLC at the time of the analysis. XQ is an employee of and owns equity in Janssen Research & Development, LLC. IN is an employee of Janssen Research & Development, LLC. MQ an employee of and owns equity in Janssen Research & Development, LLC. M-VM has received honoraria for lectures and advisory boards from AbbVie, Adaptive, Amgen, bluebird bio, BMS/Celgene, GSK, Janssen, Oncopeptides, Pfizer, Regeneron, Roche, Sanofi, Sea-Gen and Takeda. HN, WL, SG, SK, MF, JL and HM have no conflicts of interest to disclose.

Contributions

All authors contributed to the study design, study execution, data analysis, and manuscript writing. All authors provided a full review of the article and are fully responsible for all content and editorial decisions, were involved in all stages of manuscript development, and have approved the final version.

Acknowledgments

Medical writing and editorial support were provided by Austin Horton, PhD, of Cello Health Communications/MedErgy, and were funded by Janssen Global Services, LLC.

Funding

This study (clinicaltrials.gov Identifier: NCT03277105) was sponsored by Janssen Research & Development, LLC.

Data-sharing statement

The data sharing policy of Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at http://yoda.yale.edu

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