# Subcutaneous Isatuximab Administration by an On-Body Delivery System in Combination With Pomalidomide-Dexamethasone in Relapsed/Refractory Multiple Myeloma Patients: Interim Phase 1b Study Results

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## INTRODUCTION

- The anti-CD38 monoclonal antibody isatuximab (Isa) binds to a specific epitope of CD38 and kills multiple myeloma (MM) cells through multiple mechanisms of action[1,2]
- Intravenous (IV) Isa in combination with pomalidomide and dexamethasone (Pd) is approved in several countries for the treatment of patients with relapsed/refractory MM (RRMM) who have received ≥2 prior therapies, including lenalidomide and a proteasome inhibitor, based on results of the Phase 3 ICARIA study[3-5]
- Subcutaneous (SC) delivery of Isa would optimize convenience of administration, with the intent to enhance comfort and quality of life of the patients, and reduce health care resources
- This Phase 1b study evaluated safety, pharmacokinetics (PK), and efficacy of SC vs IV Isa in combination with Pd (Isa-Pd) for patients with RRMM after ≥2 prior treatment lines[7]
- Findings from the first cohorts of the study have shown that SC Isa administered by syringe pump has efficacy and safety profiles comparable to IV Isa. Isa 1400 mg was selected as the recommended Phase 2 dose (RP2D) in combination with Pd[7]
- We report here the results from an expansion cohort of patients treated with SC Isa administered at the RP2D via an on-body delivery system (OBDS), a wearable bolus injector applied to the abdomen by a healthcare professional (**Figure 1**)

**Figure 1.** Isa administration by OBDS. A) Wearable injector. B) Injector applied to the patient's abdomen[a]




[a]CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use. Isa, isatuximab; OBDS, on-body delivery system

## METHODS

### Study design and endpoints

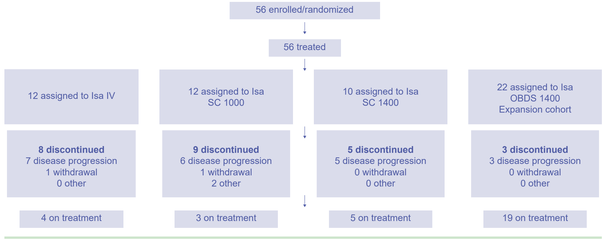
- In this multicenter, open-label, Phase 1b study (NCT04045795), patients were randomized 2:1 by sequential assignment to an Isa SC1000 mg or IV 10 mg/kg cohort and to an Isa SC1400 mg or IV 10 mg/kg cohort
- In the first cohorts, both Isa SC1000 mg and SC1400 mg were delivered through a syringe pump
- An expansion cohort was later implemented with SC Isa administered at the RP2D (1400 mg) via OBDS
- IV and SC Isa were given once weekly (QW) for 4 weeks (Cycle 1) and then once every 2 weeks (Q2W) in subsequent cycles, in combination with Pd
- The primary endpoints were safety, including dose-limiting toxicity (DLT) and injection site reactions (ISRs), as well as PK
- The main secondary endpoints were overall response rate (ORR), progression-free survival (PFS), and CD38 receptor occupancy. ORR was defined as the proportion of patients with stringent complete response (sCR), complete response (CR), very good partial response (VGPR), and partial response (PR) using the International Myeloma Working Group response criteria[6]

## RESULTS

### Patient disposition and baseline characteristics

- A total of 56 patients were randomized and treated: 12 with Isa IV, 12 with Isa SC1000, 10 with Isa SC1400, and 22 with Isa OBDS at the RP2D, in combination with Pd (**Figure 2**)

**Figure 2.** Patient disposition




- At the data cut-off (Jan 20, 2022), 4 (33%) IV, 3 (25%) SC1000, 5 (50%) SC1400, and 19 (86%) OBDS patients remained on treatment
- The median follow-up was longer in IV (20.6 months), SC1000 (23.8 months), and SC1400 (18.1 months) than in OBDS (6.5 months) patients, due to the sequential accrual
- At study entry, ISS stage II–III was 67% in IV, 33% in SC1000, 60% in SC1400, and 50% in OBDS patients (**Table 1**)
- Similar to the other cohorts, OBDS patients had received multiple treatment lines with a median of 3 (range, 2–6) and the majority were refractory to lenalidomide (95.5%), a proteasome inhibitor (72.7%), or both (72.7%)

**Table 1.** Patient demographic and baseline characteristics

| Patients, n (%) | Isa IV 10 mg/kg + Pd (n=12) | Isa SC 1000 mg + Pd (n=12) | Isa SC 1400 mg + Pd (n=10) | Isa OBDS + Pd (n=22) |
|---|---|---|---|---|
| **Age in years** | | | | |
| Median, range | 69.5 (46–83) | 67.0 (50–78) | 72.5 (63–83) | 64.5 (43–82) |
| **Age in years by category, n (%)** | | | | |
| <65 | 5 (41.7) | 5 (41.7) | 1 (10.0) | 11 (50.0) |
| ≥65 to <75 | 4 (33.3) | 6 (50.0) | 6 (60.0) | 7 (31.8) |
| ≥75 | 3 (25.0) | 1 (8.3) | 3 (30.0) | 4 (18.2) |
| **Bone marrow plasma cells (%) at baseline** | | | | |
| Median | 7.50 | 9.00 | 18.50 | 10.50 |
| **Number of bone lesions, n (%)** | | | | |
| No lesion | 4 (33.3) | 2 (16.7) | 1 (10.0) | 3 (13.6) |
| 1–4 | 4 (33.3) | 6 (50.0) | 2 (20.0) | 10 (45.5) |
| 5–10 | 1 (8.3) | 2 (16.7) | 2 (20.0) | 2 (9.1) |
| >10 | 3 (25.0) | 2 (16.7) | 5 (50.0) | 7 (31.8) |
| **Beta-2 microglobulin (mg/L)** | | | | |
| Median | 2.90 | 2.65 | 3.55 | 2.95 |
| **ISS stage at study entry, n (%)** | | | | |
| Stage I | 4 (33.3) | 8 (66.7) | 4 (40.0) | 11 (50.0) |
| Stage II | 6 (50.0) | 4 (33.3) | 6 (60.0) | 9 (40.9) |
| Stage III | 2 (16.7) | 0 | 0 | 2 (9.1) |
| **eGFR (MDRD equation)** | | | | |
| ≥90 mL/min/1.73 m$^2$ | 4 (33.3) | 4 (33.3) | 1 (10.0) | 2 (9.1) |
| 60 ≤ GFR <90 mL/min/1.73 m$^2$ | 5 (41.7) | 6 (50.0) | 5 (50.0) | 14 (63.6) |
| 30 ≤ GFR <60 mL/min/1.73 m$^2$ | 3 (25.0) | 2 (16.7) | 4 (40.0) | 6 (27.3) |
| **Number of prior lines** | | | | |
| Median, range | 3.5 (2–7) | 3.0 (2–6) | 2.5 (1–4) | 3.0 (2–6) |
| **Number of prior lines, n (%)** | | | | |
| 1 | 0 | 0 | 1 (10.0)[a] | 0 |
| 2 | 3 (25.0) | 4 (33.3) | 4 (40.0) | 4 (18.2) |
| ≥3 | 9 (75.0) | 8 (66.7) | 5 (50.0) | 18 (81.8) |
| **Refractory to, n (%)** | | | | |
| Lenalidomide | 7 (58.3) | 11 (91.7) | 7 (70.0) | 21 (95.5) |
| PI | 7 (58.3) | 9 (75.0) | 5 (50.0) | 16 (72.7) |
| IMiD and PI | 6 (50.0) | 8 (66.7) | 4 (40.0) | 16 (72.7) |

[a]Retrospective correction of treatment history for this patient, after inclusion. d, dexamethasone; eGFR, estimated glomerular filtration rate; IMiD, immunomodulatory drug; Isa, isatuximab; ISS, International Staging System; IV, intravenous; MDRD, modification of diet in renal disease; OBDS, on-body delivery system; P, pomalidomide; PI, proteasome inhibitor; SC, subcutaneous

### Safety

- An overview of the safety findings is shown in **Table 2** for each study cohort
- The incidence of all-causality Grade ≥3 treatment-emergent adverse events (TEAEs) was comparable across cohorts
- The lower incidence of Grade 3–4 treatment-related TEAEs in OBDS (77%) versus the other cohorts (≥80%) may be due to the shorter follow-up
- Overall, none of the patients had a premature discontinuation of Isa due to a TEAE; 3 (1 SC1000, 2 SC1400) patients and 2 (SC1400) patients prematurely discontinued pomalidomide and dexamethasone, respectively, due to a TEAE

**Table 2.** Safety summary

| | Isa IV 10 mg/kg + Pd (n=12) | Isa SC 1000 mg + Pd (n=12) | Isa SC 1400 mg + Pd (n=10) | Isa OBDS + Pd (n=22) | Isa OBDS and SC 1400 (RP2D[a]) + Pd (n=32) |
|---|---|---|---|---|---|
| Any TEAE | 12 (100) | 12 (100) | 10 (100) | 22 (100) | 32 (100) |
| Grade 3–4 TEAE | 12 (100) | 11 (91.7) | 9 (90.0) | 22 (100) | 31 (96.9) |
| Grade 5 TEAE[a] | 0 | 0 | 0 | 2 (9.1) | 2 (6.3) |
| Treatment-related TEAE | 12 (100) | 12 (100) | 9 (90) | 20 (90.9) | 29 (90.6) |
| Treatment-related Grade 3–4 TEAE | 10 (83.3) | 11 (91.7) | 8 (80.0) | 17 (77.3) | 25 (78.1) |
| Any serious TEAE | 9 (75.0) | 9 (75.0) | 7 (70.0) | 11 (50.0) | 18 (56.3) |
| Any serious treatment-related TEAE | 2 (16.7) | 3 (25.0) | 5 (50.0) | 2 (9.1) | 7 (21.9) |
| TEAE leading to premature treatment discontinuation | 0 | 1 (8.3) | 3 (30.0) | 0 | 3 (9.4) |
| Isatuximab | 0 | 0 | 0 | 0 | 0 |
| Pomalidomide | 0 | 1 (8.3) | 2 (20.0) | 0 | 2 (6.3) |
| Dexamethasone | 0 | 0 | 2 (20.0) | 0 | 2 (6.3) |
| Any AESI[b] | 3 (25.0) | 3 (25.0) | 2 (20.0) | 2 (9.1) | 4 (12.5) |
| Any AESI Grade ≥3 | 0 | 1 (8.3) | 1 (10.0) | 0 | 1 (3.1) |

[a]Two patients died during the on-treatment period, due to disease progression and to cardio-respiratory arrest not related to treatment (n=1 each). [b]AESI were mainly skin carcinoma in Australian patients. [c]The combination of the Isa SC1400 and OBDS cohorts is displayed as the dose administered in these cohorts (1400 mg) was the same. AESI, adverse event of special interest; d, dexamethasone; Isa, isatuximab; IV, intravenous; OBDS, on-body delivery system; P, pomalidomide; RP2D, recommended Phase 2 dose; SAE, serious adverse event; SC, subcutaneous; TEAE, treatment-emergent adverse event

- Among OBDS patients, the most common Grade ≥3 TEAEs were neutropenia (77.3%) and anemia (13.6%). However, only 1 (4.5%) patient in this cohort developed febrile neutropenia (**Table 3**)
- Infusion/injection reactions (IRs) were infrequent as they were reported in ≤10% of patients in each cohort, all Grade 2, only at first IV infusion or SC injection. No IRs occurred in OBDS patients
- Local tolerability of OBDS was very good, with 5 (22.7%) patients experiencing 7 ISR episodes (per customized MedDRA query grouping), all Grade 1, out of 305 administrations (2.3%): 5 injection site erythemas, 1 injection site hemorrhage, and 1 injection site induration. Median duration of OBDS injection was 10 min at first and subsequent administrations

**Table 3.** Any-grade TEAEs in >25% of patients by primary system organ class (including selected preferred terms)

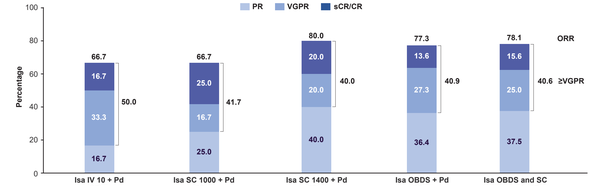
| Primary system organ class<br>Preferred term<br>n (%) | Isa IV 10 mg/kg + Pd (n=12) | | Isa SC 1000 mg + Pd (n=12) | | Isa SC 1400 mg + Pd (n=10) | | Isa OBDS + Pd (n=22) | |
|---|---|---|---|---|---|---|---|---|
| | All grades | Grade ≥3 | All grades | Grade ≥3 | All grades | Grade ≥3 | All grades | Grade ≥3 |
| Any event | 12 (100) | 12 (100) | 12 (100) | 11 (91.7) | 10 (100) | 9 (90.0) | 22 (100) | 22 (100) |
| Infections and infestations | 7 (58.3) | 3 (25.0) | 9 (75.0) | 3 (25.0) | 8 (80.0) | 4 (40.0) | 6 (27.3) | 5 (22.7) |
| Blood and lymphatic system disorders | 10 (83.3) | 10 (83.3) | 11 (91.7) | 10 (83.3) | 8 (80.0) | 8 (80.0) | 19 (86.4) | 19 (86.4) |
| Neutropenia | 10 (83.3) | 10 (83.3) | 9 (75.0) | 9 (75.0) | 7 (70.0) | 7 (70.0) | 17 (77.3) | 17 (77.3) |
| Anemia | 3 (25.0) | 2 (16.7) | 4 (33.3) | 2 (16.7) | 3 (30.0) | 1 (10.0) | 3 (13.6) | 3 (13.6) |
| Thrombocytopenia | 2 (16.7) | 2 (16.7) | 1 (8.3) | 1 (8.3) | 1 (10.0) | 1 (10.0) | 2 (9.1) | 2 (9.1) |
| Febrile neutropenia | 1 (8.3) | 1 (8.3) | 0 | 0 | 2 (20.00) | 2 (20.0) | 1 (4.5) | 1 (4.5) |
| Metabolism and nutrition disorders | 3 (25.0) | 0 | 7 (58.3) | 2 (16.7) | 4 (40.0) | 0 | 4 (18.2) | 1 (4.5) |
| Psychiatric disorders | 3 (25.0) | 2 (16.7) | 9 (75.0) | 3 (25.0) | 5 (50.0) | 2 (20.0) | 6 (27.3) | 3 (13.6) |
| Insomnia | 2 (16.7) | 2 (16.7) | 4 (33.3) | 2 (16.7) | 2 (20.0) | 2 (20.0) | 4 (18.2) | 2 (9.1) |
| Altered mood | 1 (8.3) | 1 (8.3) | 0 | 0 | 3 (30.0) | 1 (10.0) | 2 (9.1) | 2 (9.1) |
| Nervous system disorders | 7 (58.3) | 0 | 8 (66.7) | 0 | 4 (40.0) | 0 | 9 (40.9) | 2 (9.1) |
| Eye disorders | 2 (16.7) | 0 | 2 (16.7) | 1 (8.3) | 3 (30.0) | 0 | 2 (9.1) | 0 |
| Cardiac disorders | 0 | 0 | 4 (33.3) | 3 (25.0) | 3 (30.0) | 0 | 2 (9.1) | 1 (4.5) |
| Atrial fibrillation | 0 | 0 | 2 (16.7) | 2 (16.7) | 1 (10.0) | 0 | 0 | 0 |
| Vascular disorders | 2 (16.7) | 0 | 6 (50.0) | 0 | 5 (50.0) | 1 (10.0) | 2 (9.1) | 0 |
| Respiratory, thoracic, and mediastinal disorders | 6 (50.0) | 0 | 5 (41.7) | 0 | 4 (40.0) | 0 | 7 (31.8) | 2 (9.1) |
| Dyspnea | 3 (25.0) | 0 | 1 (8.3) | 0 | 2 (20.0) | 0 | 2 (9.1) | 1 (4.5) |
| Cough | 3 (25.0) | 0 | 1 (8.3) | 0 | 0 | 0 | 1 (4.5) | 0 |
| Gastrointestinal disorders | 10 (83.3) | 1 (8.3) | 11 (91.7) | 0 | 8 (80.0) | 0 | 11 (50.0) | 0 |
| Constipation | 2 (16.7) | 0 | 7 (58.3) | 0 | 1 (10.0) | 0 | 6 (27.3) | 0 |
| Diarrhea | 4 (33.3) | 0 | 5 (41.7) | 0 | 6 (60.0) | 0 | 3 (13.6) | 0 |
| Nausea | 4 (33.3) | 1 (8.3) | 5 (41.7) | 0 | 2 (20.0) | 0 | 3 (13.6) | 0 |
| Skin and subcutaneous tissue disorders | 5 (41.7) | 0 | 6 (50.0) | 0 | 2 (20.0) | 0 | 4 (18.2) | 0 |
| Musculoskeletal and connective tissue disorders | 7 (58.3) | 0 | 10 (83.3) | 2 (16.7) | 7 (70.0) | 0 | 11 (50.0) | 1 (4.5) |
| Back pain | 4 (33.3) | 0 | 4 (33.3) | 1 (8.3) | 3 (30.0) | 0 | 4 (18.2) | 0 |
| General disorders and administration site conditions | 9 (75.0) | 2 (16.7) | 9 (75.0) | 1 (8.3) | 9 (90.0) | 2 (20.0) | 15 (68.2) | 2 (9.1) |
| Injury, poisoning, and procedural complications | 6 (50.0) | 2 (16.7) | 5 (41.7) | 2 (16.7) | 3 (30.0) | 0 | 4 (18.2) | 1 (4.5) |
| Infusion reaction | 1 (8.3) | 0 | 1 (8.3) | 0 | 1 (10.0) | 0 | 0 | 0 |

d, dexamethasone; Isa, isatuximab; IV, intravenous; OBDS, on-body delivery system; P, pomalidomide; SC, subcutaneous; TEAE, treatment-emergent adverse event

### Efficacy

- Best overall responses are presented in **Figure 3** for each cohort. The ORR ranged from 67% to 80% across cohorts and the ≥VGPR rate from 40% to 50%
- The ORR in patients treated at the RP2D (SC1400 and OBDS cohorts) was 78.1%
- A longer follow-up is needed for patients in the OBDS cohort
- The estimated median PFS was 22 (95% CI, 2.3–not calculable [NC]) months in IV, 12.5 (95% CI, 5.6–NC) months in SC1000 and not reached in SC1400 (95% CI, 5.6–NC) and OBDS (95% CI, 5.6–NC) patients

**Figure 3.** Best overall responses

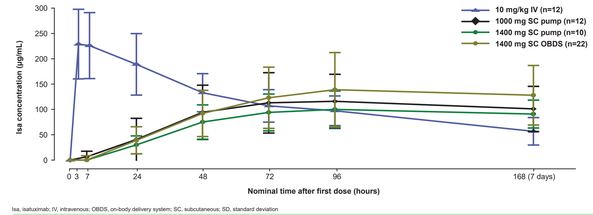



CR, complete response; d, dexamethasone; Isa, isatuximab; IV, intravenous; OBDS, on-body delivery system; ORR, overall response rate; P, pomalidomide; PR, partial response; RP2D, recommended Phase 2 dose; SC, subcutaneous; sCR, stringent complete response; VGPR, very good partial response

### PK and CD38 receptor occupancy

- PK was comparable between the SC cohorts after Isa 1000 mg and 1400 mg first dose, whichever the SC delivery method used, likely due to unbalanced distribution of PK influential covariates between the SC1000 and SC1400 cohorts (**Figure 4**)
- Mean $C_{trough}$ at the end of the weekly dosing period (best PK predictor of efficacy) was higher after Isa 1400 mg via OBDS and pump than with Isa 10 mg/kg IV
- High CD38 receptor occupancy saturation by Isa on bone marrow plasma cells was reached for all SC and OBDS cohorts (**Table** 4)

**Figure 4.** Mean (±SD) concentration-time profiles of Isa after first IV or SC administration




Isa, isatuximab; IV, intravenous; OBDS, on-body delivery system; SC, subcutaneous; SD, standard deviation

**Table 4.** CD38 receptor occupancy on bone marrow plasma cells (Day 1/Cycle 2 before dosing)

| | Isa IV 10 mg/kg + Pd (n=12) | Isa SC 1000 mg + Pd (n=12) | Isa SC 1400 mg + Pd (n=10) | Isa OBDS + Pd (n=22) | Isa OBDS and SC 1400 (RP2D) + Pd (n=32) |
|---|---|---|---|---|---|
| CD38 RO | | | | | |
| Analyzed sample, n (%) | 6 (50.0) | 5 (41.7) | 7 (70.0) | 14 (63.6) | 21 (65.6) |
| Mean, % (SD) | 76.0 (6.5) | 79.8 (3.4) | 80.5 (1.7) | 77.7 (5.4) | 78.6 (4.7) |
| Median, % | 73.9 | 80.2 | 80.2 | 78.1 | 79.1 |
| Min; Max, % | 68.2; 86.1 | 74.7; 84.2 | 78.6; 83.2 | 64.2; 85.4 | 64.2; 85.4 |

d, dexamethasone; Isa, isatuximab; IV, intravenous; Min, minimum; Max, maximum; OBDS, on-body delivery system; P, pomalidomide; RP2D, recommended Phase 2 dose; SC, subcutaneous; SD, standard deviation

## CONCLUSIONS

- SC Isa administered by OBDS at the RP2D of 1400 mg has shown a safety profile consistent with IV administration, with no IRs and excellent local tolerability
- The efficacy achieved in the SC cohorts by Isa in combination with Pd was comparable to that observed in the pivotal Phase 3 study ICARIA with IV Isa
- PK and CD38 receptor occupancy results in OBDS patients were similar to those observed in patients receiving Isa SC 1400 mg with pump
- Isa SC administration by OBDS is well tolerated, requires a short duration of injection, and provides a convenient hands-free option

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