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## 652.MULTIPLE MYELOMA: CLINICAL AND EPIDEMIOLOGICAL

# Real-World Analysis of Treatment Patterns and the Effectiveness and Safety Profile of Daratumumab-Based Regimens in Chinese Patients with Newly Diagnosed or Relapsed/Refractory Multiple Myeloma

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Introduction: Daratumumab (DARA) is a human IgG$\kappa$ monoclonal antibody targeting CD38 with a direct on-tumor and immunomodulatory mechanism of action. Several clinical trials have established DARA-based treatment as a standard of care globally for patients with newly diagnosed or relapsed/refractory multiple myeloma (MM). However, clinical trials do not always reflect routine clinical practice, and real-world (RW) studies thus provide an important complement to conventional clinical trials. Herein, we report results from an observational study that described RW treatment patterns and outcomes in routine clinical practice among patients with MM who were treated with DARA in China. This is possibly the first study to enroll a large population of Chinese patients with MM who were treated with DARA in the RW setting.
Methods: This ongoing, multicenter, noninterventional, observational registry study is enrolling Chinese patients who have been diagnosed with symptomatic newly diagnosed or relapsed/refractory MM and either (1) started DARA treatment after August 1, 2019, and were expected to continue ongoing DARA at the time of study initiation (November 3, 2021) or (2) started DARA treatment after study initiation. Patients were excluded from the study if they had received ≥4 prior lines of MM therapy before starting DARA-based treatment or had a diagnosis of other cancers prior to their MM diagnosis. The decision to treat with DARA must have been made prior to and independently of the patient's inclusion in the study, and treatment was administered in accordance with local clinical practice. For patients who started DARA after August 1, 2019, but before study initiation, data were collected both retrospectively through medical chart review and prospectively after enrollment. RW baseline disease characteristics, treatment patterns, response rates, measurable residual disease (MRD), and safety are presented. Outcome and safety analyses were based on the DARA treatment period.
Results: As of the cutoff date (April 30, 2023) for this analysis, 210 patients who received ≥1 dose of DARA have been enrolled in the study from 13 participating sites in China. At baseline (last status prior to the first DARA dose), patients had a median age of 64 y (range, 29-89) and a median time since MM diagnosis of 1 y (range, 0-12); the majority of patients had an ECOG performance status of 0 or 1 (82.4%) and a Durie-Salmon MM stage of III (74.4%). Most (83.8%) patients had received ≥1 prior

line of therapy before initiating DARA, including 82.4% who had received prior protease inhibitors (PIs) and 58.1% who had received prior immunomodulatory drugs (IMiDs). A summary of prior therapies is provided in *Table 1*. DARA-based therapy included DARA monotherapy (n = 22) or combination with dexamethasone only (n = 21), PIs ± dexamethasone (n = 57), IMiDs ± dexamethasone (n = 71), PIs and IMiDs ± dexamethasone (n = 29), and other combinations (n = 10). The median DARA exposure time was 5.39 mo (interquartile range [IQR], 2.56-9.69), and the median follow-up time was 10.48 mo (IQR, 7.23-15.31).

Of the 179 patients evaluable for response, a best overall response of partial response (PR) or better was achieved by 130 (72.6%) patients and a best response of very good partial response (VGPR) or better was achieved by 93 (52.0%) patients, with responses observed across DARA treatment regimens ( *Table 2*). MRD results were available for 53/179 (29.6%) patients, with 31/53 (58.5%) patients achieving MRD negativity. Adverse drug reactions were reported for 40 (19.0%) patients overall; events reported in ≥5% of patients included leukopenia (6.2%), thrombocytopenia (5.7%), and neutropenia (5.2%). Serious treatment-emergent adverse events were reported for 29 (13.8%) patients, with pneumonia (n = 10, 4.8%) the only serious event reported in ≥5 patients. Twenty-five patients died as of the cut-off date, regardless of timing (with/without DARA treatment period).

Conclusions: This noninterventional, observational study provides RW insights into physician treatment decisions for patients with MM in China and the characteristics of patients who are selected for DARA-based treatment. In addition, the RW effectiveness, duration of therapy, and safety results support the use of DARA-based treatment as a standard of care in Chinese patients with newly diagnosed or relapsed/refractory MM. This study is ongoing, with a total planned enrollment of ~220 patients.

**Disclosures Li:** *Janssen (China) Research & Development Center:* Current Employment. **Yang:** *Janssen (China) Research & Development Center:* Current Employment. **Zhuo:** *Janssen (China) Research & Development Center:* Current Employment. **Chen:** *Xian Janssen Pharmaceutical Ltd.:* Current Employment, Current holder of *stock options* in a privately-held company. **Cui:** *Xian Janssen Pharmaceutical Ltd.:* Current Employment, Current holder of *stock options* in a privately-held company. **Lu:** *Jassen Pharmaceutical Ltd:* Consultancy, Speakers Bureau.

Table 1. Summary of Prior Non-DARA Regimens for MM

| n (%) | Overall (n = 210) | DARA mono (n = 22) | DARA + dexa (n = 21) | DARA + PIs (± dexa) (n = 57) | DARA + IMiDs (± dexa) (n = 71) | DARA + PIs + IMiDs (± dexa) (n = 29) | DARA + other agents (n = 10) |
|---|---|---|---|---|---|---|---|
| Number of prior non-DARA MM therapies | | | | | | | |
| 0 | 34 (16.2) | 3 (13.6) | 3 (14.3) | 14 (24.6) | 6 (8.5) | 8 (27.6) | 0 |
| 1 | 111 (52.9) | 6 (27.3) | 12 (57.1) | 29 (50.9) | 44 (62.0) | 14 (48.3) | 6 (60.0) |
| 2 | 41 (19.5) | 6 (27.3) | 5 (23.8) | 8 (14.0) | 15 (21.1) | 5 (17.2) | 2 (20.0) |
| 3 | 24 (11.4) | 7 (31.8) | 1 (4.8) | 6 (10.5) | 6 (8.5) | 2 (6.9) | 2 (20.0) |
| Prior non-DARA MM therapies | | | | | | | |
| PIs | 173 (82.4) | 19 (86.4) | 18 (85.7) | 42 (73.7) | 63 (88.7) | 21 (72.4) | 10 (100) |
| Bortezomib | 169 (80.5) | 18 (81.8) | 17 (81.0) | 42 (73.7) | 61 (85.9) | 21 (72.4) | 10 (100) |
| Carfilzomib | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (3.4) | 0 |
| Ixazomib | 42 (20.0) | 10 (45.5) | 4 (19.0) | 7 (12.3) | 16 (22.5) | 4 (13.8) | 1 (10.0) |
| IMiDs | 122 (58.1) | 16 (72.7) | 10 (47.6) | 22 (38.6) | 51 (71.8) | 15 (51.7) | 8 (80.0) |
| Lenalidomide | 109 (51.9) | 13 (59.1) | 10 (47.6) | 19 (33.3) | 47 (66.2) | 13 (44.8) | 7 (70.0) |
| Pomalidomide | 17 (8.1) | 5 (22.7) | 1 (4.8) | 4 (7.0) | 3 (4.2) | 2 (6.9) | 2 (20.0) |
| Thalidomide | 25 (11.9) | 4 (18.2) | 4 (19.0) | 5 (8.8) | 9 (12.7) | 3 (10.3) | 0 |

MM, multiple myeloma; DARA, daratumumab; mono, monotherapy; dexa, dexamethasone; PIs, protease inhibitors; IMiDs, immunomodulatory drugs.

Table 2. Summary of Best Response to DARA-based Treatment

| n (%) | Overall (n = 179) | DARA mono (n = 17) | DARA + dexa (n = 18) | DARA + PIs (± dexa) (n = 45) | DARA + IMiDs (± dexa) (n = 63) | DARA + PIs + IMiDs (± dexa) (n = 27) | DARA + other agents (n = 9) |
|---|---|---|---|---|---|---|---|
| VGPR or better | 93 (52.0) | 5 (29.4) | 9 (50.0) | 22 (48.9) | 35 (55.6) | 16 (59.3) | 6 (66.7) |
| ORR (PR or better) | 130 (72.6) | 10 (58.8) | 13 (72.2) | 32 (71.1) | 48 (76.2) | 19 (70.4) | 8 (88.9) |
| Response category | | | | | | | |
| sCR | 5 (2.8) | 0 | 1 (5.6) | 0 | 0 | 3 (11.1) | 1 (11.1) |
| CR | 50 (27.9) | 2 (11.8) | 6 (33.3) | 11 (24.4) | 24 (38.1) | 4 (14.8) | 3 (33.3) |
| VGPR | 38 (21.2) | 3 (17.6) | 2 (11.1) | 11 (24.4) | 11 (17.5) | 9 (33.3) | 2 (22.2) |
| PR | 37 (20.7) | 5 (29.4) | 4 (22.2) | 10 (22.2) | 13 (20.6) | 3 (11.1) | 2 (22.2) |
| MR | 4 (2.2) | 2 (11.8) | 0 | 1 (2.2) | 1 (1.6) | 0 | 0 |
| SD | 17 (9.5) | 2 (11.8) | 1 (5.6) | 5 (11.1) | 5 (7.9) | 4 (14.8) | 0 |
| PD or clinical relapse | 13 (7.3) | 0 | 1 (5.6) | 5 (11.1) | 6 (9.5) | 0 | 1 (11.1) |
| MRD performed | 53 | 2 | 2 | 14 | 20 | 11 | 4 |
| Ever had MRD-negative result | 31 (58.5) | 0 | 0 | 9 (64.3) | 11 (55.0) | 7 (63.6) | 4 (100) |

DARA, daratumumab; mono, monotherapy; dexa, dexamethasone; PIs, protease inhibitors; IMiDs, immunomodulatory drugs; VGPR, very good partial response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; CR, complete response; MR, minimal response; SD, stable disease; PD, progressive disease; MRD, measurable residual disease.

**Figure 1**

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