Abstract: P968

Title: FINAL SURVIVAL ANALYSIS OF DARATUMUMAB PLUS LENALIDOMIDE AND DEXAMETHASONE VERSUS LENALIDOMIDE AND DEXAMETHASONE IN TRANSPLANT-INELIGIBLE PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA: MAIA STUDY

Abstract Type: Poster Presentation

Topic: Myeloma and other monoclonal gammopathies - Clinical

Background:

The inclusion of daratumumab (DARA) in frontline combination therapy has consistently demonstrated clinical efficacy in patients with newly diagnosed multiple myeloma (NDMM). With a median follow-up of 64.5 months in the phase 3 MAIA study (NCT02252172), transplant-ineligible (TIE) patients with NDMM who were treated with DARA plus lenalidomide/dexamethasone (D-Rd) had superior progression-free survival (PFS; median of 61.9 vs 34.4 months) and overall survival (OS; median not reached vs 65.5 months) versus lenalidomide/dexamethasone (Rd) alone.

Aims:

This long-term follow-up analysis of MAIA reports updated OS results for D-Rd versus Rd and new data on subsequent antimyeloma therapies after a median follow-up of 7.5 years.

Methods:

Patients with NDMM ineligible for high-dose chemotherapy and autologous stem cell transplantation due to age ≥65 years or comorbidities were randomized 1:1 to receive D-Rd or Rd. All patients received 28-day cycles of Rd (R: 25 mg orally once daily on Days 1-21; d: 40 mg orally on Days 1, 8, 15 and 22) with or without DARA (16 kg/mg IV once weekly for Cycles 1-2, once every 2 weeks for Cycles 3-6, and every 4 weeks thereafter) until disease progression or unacceptable toxicity. The primary endpoint of MAIA was PFS, and OS was a key secondary endpoint.

Results:

A total of 737 patients were randomized in MAIA (D-Rd, n=368; Rd, n=369). Baseline patient characteristics were balanced between groups; the median (range) age was 73 (45-90) years, with 43.6% of patients overall aged ≥75 years.

After a median (range) follow-up of 89.3 (0-102.2) months, a 33% reduction in the risk of death was observed with D-Rd versus Rd. Median OS was 90.3 months in the D-Rd group versus 64.1 months in the Rd group (hazard ratio [HR], 0.67; 95% confidence interval [CI], 0.55-0.82; nominal P<0.0001; Figure).

Among those treated, 140/364 (38.5%) patients in the D-Rd group and 201/365 (55.1%) in the Rd group received ≥1 subsequent line of antimyeloma therapy on study, and the median time to subsequent therapy was longer in the D-Rd versus Rd group (not reached vs 42.4 months; HR, 0.51; 95% CI, 0.41-0.63; nominal P<0.0001). Among patients who received subsequent antimyeloma therapy, the most common antineoplastic agents after D-Rd and Rd, respectively, were bortezomib (27.7% vs 41.9%), DARA (6.3% vs 28.8%), and carfilzomib (7.7% vs 12.3%). Treatment with BCMA- or GPRC5D-targeted therapy was not captured in any patient. Two patients in the D-Rd group and 2 patients in the Rd group received investigational drugs in subsequent therapy lines.

Overall, 285 (78.3%) and 345 (94.5%) patients in the D-Rd and Rd groups, respectively, discontinued study treatment, primarily due to progressive disease (119 [32.7%] and 141 [38.6%]).

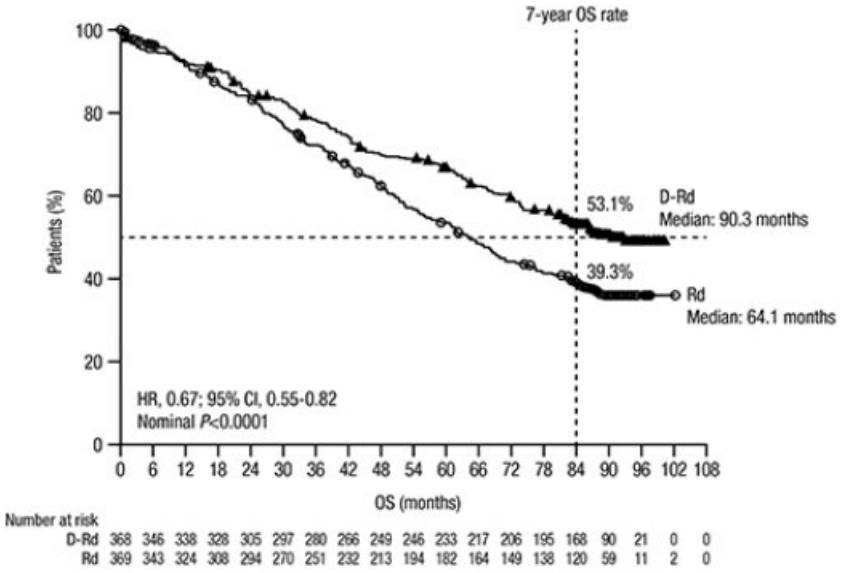
Additional data on classes of first subsequent therapy, the most common first subsequent regimens, and

causes of death will be presented.

Summary/Conclusion:

With a median follow-up of 7.5 years, D-Rd continued to demonstrate a clinically significant survival benefit versus Rd in TIE patients with NDMM. Median OS with D-Rd was 7.5 years. Furthermore, subsequent antimyeloma therapy was DARA-based in 28.8% of patients treated with Rd versus 6.3% treated with D-Rd. These data continue to support the use of frontline D-Rd to maximize survival in TIE patients with NDMM.

Figure. OS with D-Rd and Rd.



OS, overall survival; D-Rd, daratumumab plus lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; HR, hazard ratio; CI, confidence interval.

Keywords: CD38, Clinical trial, Multiple myeloma, Survival