Abstract: P882

Title: POMALIDOMIDE, DARATUMUMAB, AND DEXAMETHASONE AFTER LENALIDOMIDE TREATMENT IN PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA (RRMM): FINAL OVERALL SURVIVAL ANALYSIS OF THE PHASE 2 MM-014 STUDY

Abstract Type: Poster Presentation

Session Title: Myeloma and other monoclonal gammopathies - Clinical

Background:

Treatment (Tx) choice after first line of Tx (LoT) is important for patients (pts) with multiple myeloma (MM). The MM Tx landscape has evolved, but there is no consensus on optimal sequence. Nearly all pts with MM receive lenalidomide (LEN) in first or second LoT; pts with RRMM who have exhausted LEN benefits require improved options. The phase 2 MM-014 trial (NCT01946477) explored outcomes of pomalidomide (POM)-based Tx in early LoT for RRMM. In cohort B, at a median follow-up of 28.4 mo, POM+daratumumab (DARA)+low-dose dexamethasone (DEX; DPd) showed promising efficacy, with an overall response rate (ORR) of 77.7% and median progression-free survival of 30.8 mo (Bahlis. *Leuk Lymphoma* 2022).

Aims:

To report final overall survival (OS) in MM-014 cohort B at a median follow-up of 41.9 mo.

Methods:

MM-014 had 3 cohorts. In cohort B, pts aged ≥18 y with RRMM who had received 1–2 prior LoT with LEN-based regimen as their most recent were eligible. Pts received DPd in 28-d cycles: POM 4 mg orally daily on d 1–21; DEX 40 mg (age ≤75 y) or 20 mg orally (age >75 y) on d 1, 8, 15, and 22; DARA intravenously 16 mg/kg body weight on d 1, 8, 15, and 22 of cycles 1–2, d 1 and 15 of cycles 3–6, and d 1 of cycle 7 and beyond. The primary endpoint was ORR. OS and safety were secondary endpoints. OS was calculated as the time from start of Tx until time of death from any cause; pts were censored at the date last known to be alive. Dose interruptions and reductions were allowed for certain Tx-emergent adverse events (TEAEs). Pts were followed for OS, subsequent Tx, and second primary malignancies for up to 5 y after the last pt was enrolled.

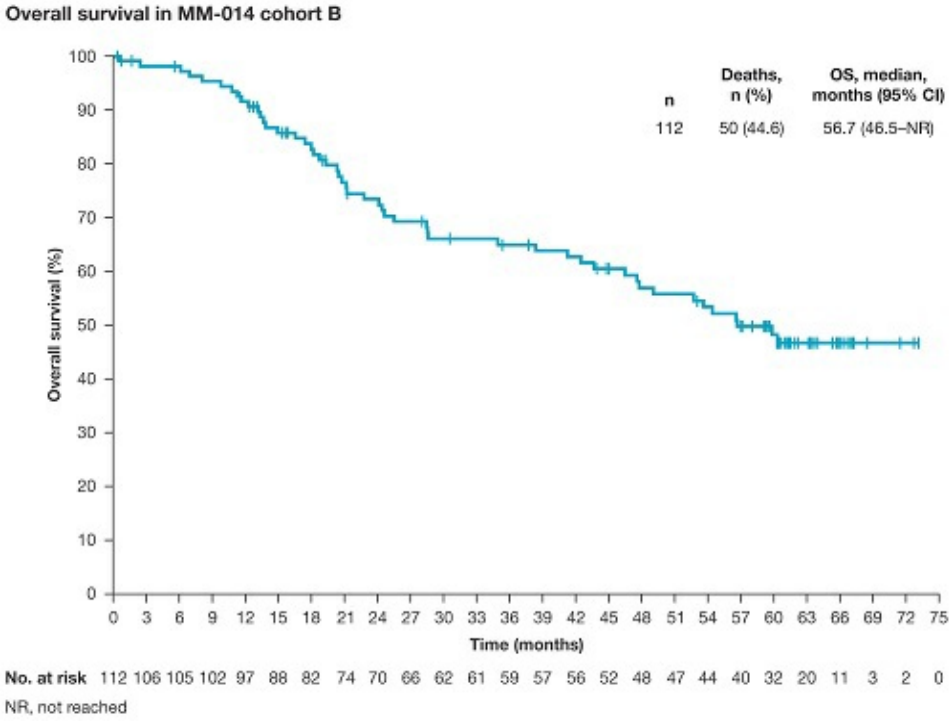
Results:

Among 112 pts enrolled in cohort B, 85 (75.9%) had disease refractory to LEN and 27 (24.1%) had relapsed disease following LEN; 69 (61.6%) and 43 (38.4%) had received 1 and 2 prior LoT, respectively. At a median follow-up of 41.9 mo (range, 0.4–73.1), 96 (85.7%) pts had discontinued Tx, mostly due to disease progression (n=54 [48.2%]). Pts received POM, DEX, and DARA for median durations of 15.7 (range, 0.3–73.1), 13.7 (range, <0.1–72.5), and 15.2 (range, <0.1–72.7) mo, respectively. Fifty (44.6%) pts died, mostly due to disease progression (n=28 [25.0%]). Median OS was 56.7 mo (95% CI, 46.5–not reached [NR]) (**Figure**). Median OS was 53.6 mo (95% CI, 28.6–NR) among pts refractory to their most recent prior LEN-based Tx and NR (95% CI, 47.6–NR) among pts who experienced relapse. TEAEs leading to discontinuation of POM, DEX, or DARA occurred in 7 (6.3%), 9 (8.0%), and 6 (5.4%) pts, respectively. Additionally, 31 (27.7%) and 38 (33.9%) pts experienced Tx-related TEAEs leading to POM and DEX reduction, respectively, while 55 (49.1%), 17 (15.2%), and 65 (58.0%) experienced Tx-related TEAEs leading to POM, DEX, and DARA interruption, respectively. Neutropenia was the most common Tx-related TEAE leading to dose modification of POM (reduction, n=17 [15.2%]; interruption, n=38 [33.9%]) and DARA (interruption, n=30 [26.8%]); insomnia was the most common Tx-related TEAE leading to dose modification of DEX (reduction, n=10 [8.9%]; interruption, n=1 [0.9%]).

Summary/Conclusion:

With long-term follow-up, pts with RRMM treated with DPd demonstrated favorable OS. The safety profile of DPd

was similar to previous reports with no new safety signals identified. These data suggest that DPd is beneficial for pts with RRMM who have exhausted benefits of LEN in earlier LoT.



Keywords: Clinical trial, Imids, Survival, Multiple myeloma