

Statistical Analysis and Findings

Following is a summary of findings from the OCEAN clinical trial.

OCEAN is a randomized, controlled, open label, multicenter trial of melphalan flufenamide and low dose dexamethasone compared to pomalidomide and low dose dexamethasone in patients with relapsed or refractory multiple myeloma following 2-4 lines of prior therapy and who are refractory to lenalidomide in the last line of therapy.

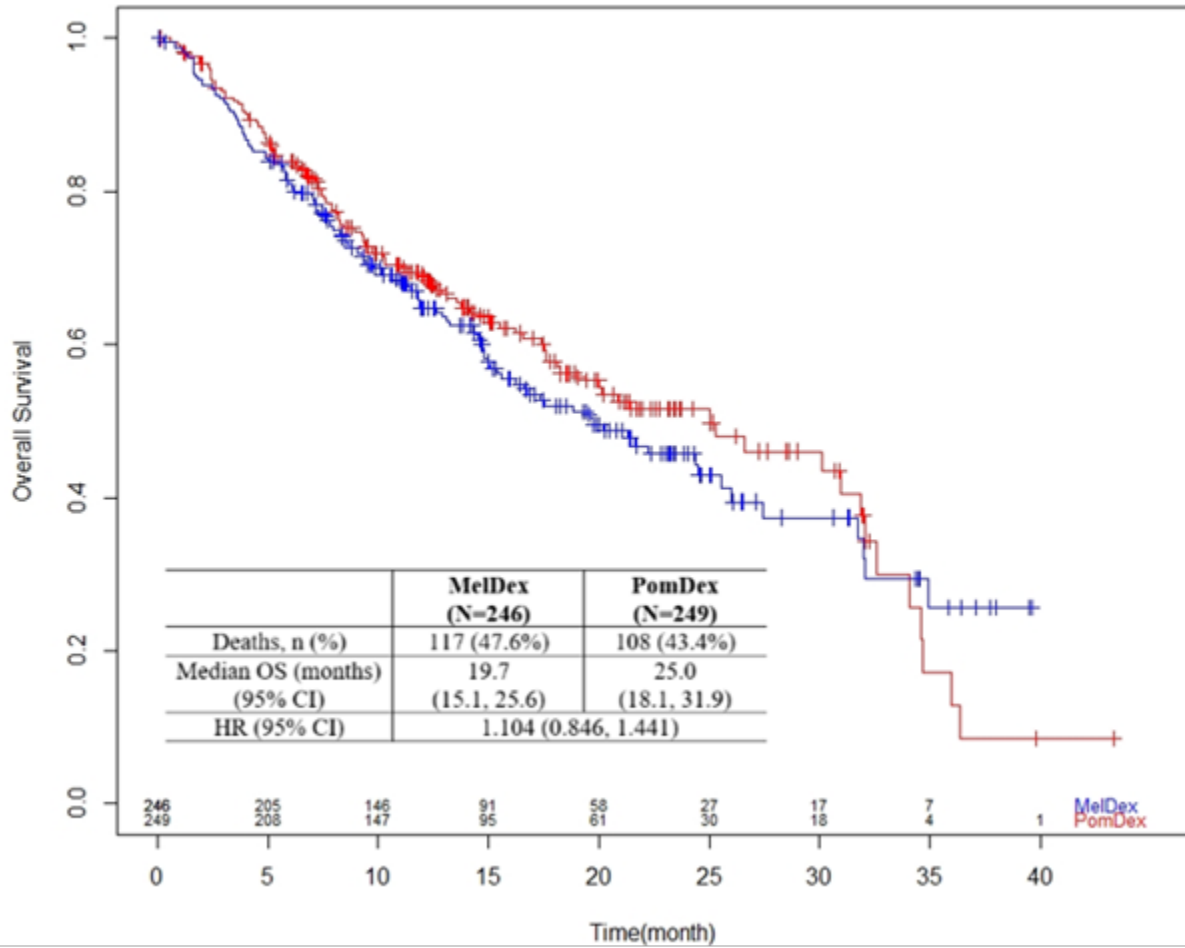
FDA conducted an efficacy and safety evaluation of the OCEAN trial using a data cut-off date of February 3, 2021. There were 495 randomized patients included in the efficacy analysis.

For overall survival, there were 117/246 (48%) deaths on the melphalan flufenamide investigational arm and 108/249 (43%) deaths on the pomalidomide control arm.

The hazard ratio (HR) for overall survival (OS) of the melphalan flufenamide containing investigational arm compared to the control arm of pomalidomide was 1.104 (95% CI: 0.846,1.441), indicating a detriment in survival in the melphalan flufenamide arm compared to the pomalidomide control arm.

The median OS in the melphalan flufenamide containing investigational arm was 19.7 months (95% CI:15.1, 25.6) compared to 25.0 months (95% CI: 18.1, 31.9) in the pomalidomide containing control arm. The median follow-up for survival was 19.1 months.

K-M Curve for OS in ITT Population



MelDex: Melflufen + Dexamethasone; PomDex: Pomalidomide + Dexamethasone
 Source: FDA analysis

Additional FDA analyses of safety and efficacy are ongoing.