ELOQUENT-1 and TOURMALINE-MM2 studies report no improvement in PFS in patients with newly diagnosed MM

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This week, data from two phase III clinical trials, ELOQUENT-1 and TOURMALINE-MM2, conducted in patients with transplant ineligible newly diagnosed multiple myeloma (NDMM), were announced. Both studies did not meet their primary endpoints, of a significant improvement in progression-free survival (PFS) with the addition of elotuzumab (E) or ixazomib (I) to the standard lenalidomide and dexamethasone (Rd) combination, respectively.[1,2]

ELOQUENT-1[1]

ELOQUENT-1 (NCT01335399) is a randomized, open-label, phase III study evaluating the combination ERd, *vs* Rd in transplant-ineligible patients with NDMM. The primary endpoint is PFS, and secondary endpoints include objective response rate and overall survival (OS).

The analysis revealed that there was no statistical improvement in PFS with ERd compared with Rd. The safety profile of ERd was consistent with that previously reported for the same combination in the relapsed and refractory setting in the ELOQUENT-2 trial. The results of a full ELOQUENT-1 data evaluation will be presented at a future medical meeting.

The ERd combination has been previously approved by the US Food and Drug Administration (FDA) and European Medicines Agency for the treatment of adult patients with MM, who received one to three prior therapies.[3,4] Elotuzumab in combination with pomalidomide and dexamethasone is also approved by the FDA and

the EMA for the treatment of adult patients after ≥ 2 prior therapies including lenalidomide and a proteasome inhibitor.[3,4] (Read about the approval by the FDA here and the European Commission here.)

TOURMALINE-MM2[2]

TOURMALINE-MM2 (NCT01850524) is a randomized, double-blind, placebo-controlled phase III clinical trial evaluating IRd *vs* placebo plus Rd, in transplant-ineligible patients with NDMM (N = 705). The primary endpoint is PFS and secondary endpoints include complete response rate and OS.

The analysis demonstrated non-significant 13.5 months improvement in PFS in the IRd group *vs* Rd group (35.3 *vs* 21.8 months; HR 0.83; p = 0.073). The safety profile was generally consistent with previous reports.[5]

Despite the study not meeting the primary endpoint with statistical significance, a 13.5-month improvement in PFS indicates the oral IRd combination may still have a role in the treatment of NDMM, specifically for patients who are older with comorbidities, or those who cannot travel easily for treatment.

The IRd combination has been previously approved by the FDA and EMA for the treatment of patients with MM who have received ≥ 1 prior therapy.[6,7] Ixazomib is also being investigated in other combinations and indications. (Read about IRd as a consolidation treatment, ixazomib in combination with thalidomide and dexamethasone for RR MM and ixazomib maintenance in NDMM).

References:

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