Article Tools

HEMATOLOGIC MALIGNANCIES—PLASMA CELL DYSCRASIA

Ixazomib plus lenalidomide-dexamethasone (IRd) vs placebo-Rd in patients (pts) with relapsed/refractory multiple myeloma (RRMM): China continuation of TOURMALINE-MM1.

Jian Hou, Jie Jin, Yan Xu, Depei Wu, Xiaoyan Ke, Zhou Daobin, ...

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Abstract Disclosures

Abstract

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Background: The global, randomized, double-blind, placebo-controlled, phase 3 TOURMALINE-MM1 study (NCT01564537) demonstrated 35% improvement in PFS (HR 0.74, p = 0.012) with IRd vs placebo-Rd in pts with RRMM (Moreau et al, ASH 2015). This continuation study assessed the efficacy and safety of IRd vs placebo-Rd in pts with RRMM in China as a separate regional expansion of the global study. **Methods:** Eligibility criteria and study design were per the global study, except high-risk cytogenetic and patient-reported outcome endpoints were not assessed. The primary endpoint was PFS, assessed by the same IRC. Pts were analyzed separately from the global study. Sample size was not based on a formal statistical hypothesis. **Results:** 115 pts were randomized (57 IRd, 58 placebo-Rd). Compared to the global study, pts had more advanced disease (63% ISS stage II/III vs 46% in the global study), were more heavily pretreated (60% vs 41% had 2 or 3 prior therapies), and more frequently had refractory MM (43% vs 11%). At data cut-off (12 July 2015; median follow-up 8.0 vs 7.8 mos), PFS was significantly improved with IRd vs placebo-Rd: median 6.7 vs 4.0 mos; HR 0.598; p = 0.035. This benefit was seen

across prespecified subgroups. Median TTP was 7.3 vs 4.1 mos with IRd vs placebo-Rd; HR = 0.583. Overall survival data were not yet mature; 6 (11%) IRd and 16 (28%) placebo-Rd pts have died. Overall response (≥ VGPR) rates were 56% (25%) vs 31% (12%). Pts had received a median of 7 and 5 cycles of IRd and placebo-Rd, and 59% and 41% of pts remained on treatment; 56% vs 62% had grade ≥ 3 AEs, 23% vs 26% had SAEs, 5% vs 12% discontinued treatment due to AEs, and 4% vs 5% died on treatment. Common grade ≥ 3 AEs with IRd vs placebo-Rd included thrombocytopenia (23% vs 13%), neutropenia (23% vs 19%), anemia (12% vs 26%), and pneumonia (16% vs 10%). 18% vs 19% of pts had rash (no grade ≥ 3 events); 7% of pts in each group had peripheral neuropathy (no grade ≥ 3 events). **Conclusions:** In Chinese pts with RRMM, IRd was associated with a significant improvement in PFS, with limited additional toxicity, demonstrating the consistent relative benefit of IRd vs placebo-Rd in this distinct Chinese population and the global study Clinical trial information: NCT01564537.