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Takeda's multiple myeloma drug meets primary endpoints

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Singapore: Japanese pharma major Takeda Pharmaceutical Company has announced that the randomized, double-blind, placebo-controlled TOURMALINE-MM1 pivotal phase 3 trial evaluating the safety and efficacy of Ixazomib, the first oral proteasome inhibitor, conducted in patients with relapsed or refractory multiple myeloma (MM) achieved its primary endpoint of improving progression-free survival at the first pre-specified interim analysis. In the trial, patients treated with investigational Ixazomib plus lenalidomide and dexamethasone lived without their disease worsening for a significantly longer time compared to patients who received placebo plus lenalidomide/dexamethasone.

Efficacy and safety data were reviewed by an Independent Data Monitoring Committee (IDMC). Takeda intends to submit this data to health authorities globally for marketing authorizations.

TOURMALINE-MM1 Study (n=722) is an international, randomized, double-blind, placebo controlled clinical trial designed to compare the efficacy and safety of two treatment regimens administered until progression - ixazomib plus lenalidomide and dexamethasone versus placebo plus lenalidomide and dexamethasone - in adult patients with relapsed and/or refractory MM. Subjects included in the study had a confirmed diagnosis of MM, received one to three prior therapies and met other outlined eligibility criteria. Patients who were refractory to lenalidomide or proteasome inhibitor-based therapy were excluded.