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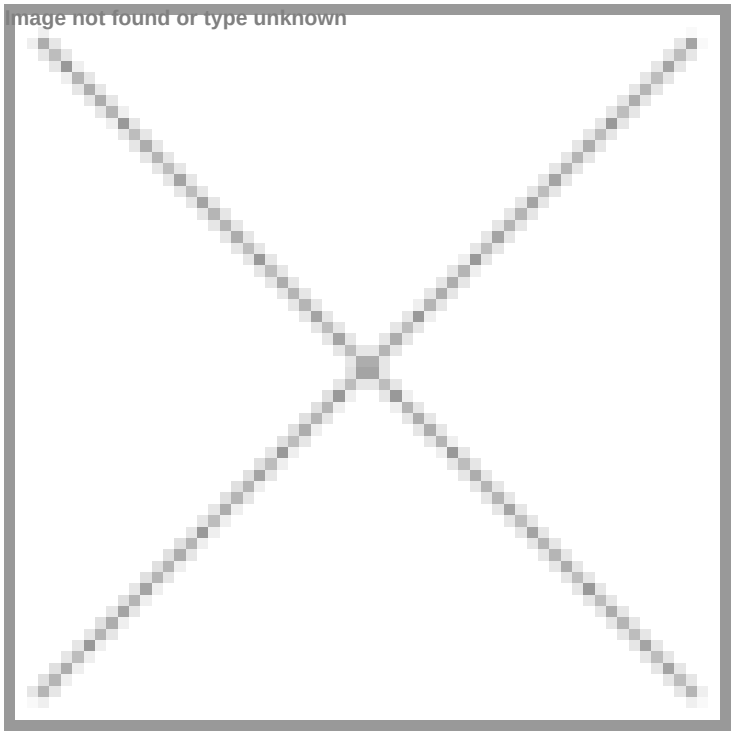
Takeda to discontinue trial in AL Amyloidosis

06 June 2019 | News

An Independent Data Monitoring Committee (IDMC) did not raise any concerns about the safety profile of NINLARO in this setting.



Takeda Pharmaceutical Company Limited has announced that the Phase 3 TOURMALINE-AL1 clinical trial in patients with relapsed or refractory systemic light-chain (AL) amyloidosis did not meet the first of two primary endpoints. Treatment with NINLARO (ixazomib) in combination with dexamethasone did not demonstrate a significant improvement in overall hematologic response compared to physician's choice of standard of care regimens. As a result of this analysis, Takeda has decided to discontinue the trial.

"While we are disappointed with this outcome, we aim to maximize our learnings from this trial and share findings with the community in hopes of helping to improve care for patients living with this devastating disease," said Phil Rowlands, Ph.D., Head, Oncology Therapeutic Area Unit, Takeda. "This has been one of the largest studies ever conducted in systemic light-chain AL amyloidosis and we are proud to have led it. This study demonstrated our dedication to this rare and traditionally difficult-to-enroll patient population and we thank the patients and investigators for their engagement and participation. We remain optimistic about NINLARO and continue to investigate NINLARO in patient populations across the continuum of multiple myeloma care."

An Independent Data Monitoring Committee (IDMC) did not raise any concerns about the safety profile of NINLARO in this setting. Patients are encouraged to consult their study investigators to address any questions.

TOURMALINE-AL1 (NCT01659658) is an international, randomized, controlled, open-label, multicenter, Phase 3 study, designed to determine whether NINLARO (ixazomib) in combination with dexamethasone improves hematologic response, 2-year vital organ (heart or kidney) deterioration and mortality rate versus a physician's choice of a chemotherapy regimen in participants diagnosed with relapsed or refractory systemic light chain (AL) amyloidosis. Patients were randomly selected to receive either NINLARO plus dexamethasone, or physician’s choice of dexamethasone plus melphalan; dexamethasone plus cyclophosphamide; dexamethasone plus thalidomide; dexamethasone plus lenalidomide; or dexamethasone alone.