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ASCO REVIEW

In This Issue

Trisenox®

A Phase I/II Study of Trisenox®, VELCADE®, and Ascorbic Acid in Relapsed/Refractory Multiple Myeloma

Abstract #7611
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A Phase 1/11 dose-escalation trial was conducted in patients with relapsed or refractory multiple myeloma (MM) to evaluate the safety and efficacy of arsenic trioxide (Trisenox®) in combination with bortezomib (VELCADE®) and ascorbic acid.

At the time of the interim analysis, 22 of a planned sample size of 27 patients had been enrolled. Median patient age was 63 years. Patients had failed a median of four prior therapies.

Data from 21 patients were evaluable for efficacy. Ten patients (43%) achieved an objective response, including two complete responses (CR), two partial responses (PR), and five minor responses (MR).

Eight of the 15 patients being administered the higher doses of bortezoinib (1.0 or 1.3 mg/m^2) responded, while only one of the six patients receiving the lowest dose (0.7 mg/m^2) responded (a minor response).

The combination of arsenic trioxide, bortezomib and ascorbic acid is generally well tolerated. One patient experienced grade 4 thrombocytopenia and one patient withdrew clue to a single occurrence of asymptomatic arrhythmia. All other adverse events were grade 1 or grade 2.

The investigators concluded that, with an objective response rate of 43% in a heavily pretreated patient population, further clinical studies of this combination regimen are warranted in patients with relapsed or refractory MM.

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