

## **Results from a Phase II Study of Isatuximab As a Single Agent and in Combination with Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma**

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Today, I will be reviewing the results from the Phase II study of isatuximab as a single agent and in combination with dexamethasone in patients with relapsed /refractory multiple myeloma.

In this particular study, patients with relapsed/refractory myeloma who have received three or more lines of therapy and who have failed at least bortezomib and lenalidomide were randomized on a 2:1 ratio to receive either single-agent isatuximab or isatuximab with weekly dexamethasone. In both arms, isatuximab was given at a dose of 20 mg/kg weekly for the first month and then every two weeks continuously until there was evidence of disease progression or unacceptable toxicity. The main finding of the study was that with the addition of dexamethasone, the response rate improved from 26% to 44% and the progression-free survival improved from 4.8 months to 7.9 months indicating that dexamethasone may have a synergistic effect with isatuximab. Furthermore, the safety profile in both arms was almost identical with very few infusion related reactions, very few patients had to discontinue therapy, and in the isatuximab and dexamethasone arm, there were some steroid related effects. Side effects such as psychiatric disorders, gastrointestinal toxicity, and increased cataracts. This data indicates that the combination of isatuximab with dexamethasone is improving the outcome of patients treated with single-agent isatuximab; and we know that in the ongoing studies with isatuximab, in the frontline setting such as with VRD/isatuximab, in the relapsed setting such as with KD/isatuximab and in the more advanced setting with pomalidomide/dexamethasone/isatuximab, in all these combinations, steroids are part of the treatment of the patients.

### **Reference**

Dimopoulos M, Bringhen S, Anttila P, et al. Results from a Phase II Study of Isatuximab As a Single Agent and in Combination with Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma. ASH 2018. Abstract 155.