MultipleMyelomaHub

Relapsed/refractory patients

# FDA approves isatuximab plus pomalidomide and dexamethasone for the treatment of relapsed or refractory multiple myeloma

**Joanna Nikitorowicz-Buniak** | Mar 03, 2020

On March 2, 2020, isatuximab-irfc in combination with pomalidomide and dexamethasone (pom-dex) was granted approval by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.[1,2] Isatuximab is a monoclonal antibody against CD38, which is highly expressed on the surface of multiple myeloma cells. Upon binding to a malignant cell, the antibody induces apoptosis and has immunomodulatory activity, leading to inhibition of cancer growth.[3]

The approval was based on the positive results of the phase III ICARIA-MM clinical trial, which demonstrated improved overall response rate (ORR) and progression free survival (PFS) with isatuximab plus pom-dex compared to pom-dex alone (ORR 60.4% *vs* 35.3%, p < 0.0001; median PFS 11.53 months *vs* 6.47 months, HR 0.596, 95% CI, 0.44–0.81, p = 0.0010).[2] You can watch Paul G. Richardson from the Dana-Farber Cancer Institute, Boston, US, discussing the results here or read about the results from a subgroup analysis by patient cytogenetics.

The most common adverse reactions of any grade, reported by more than 20% of patients, were neutropenia (96%), infusion-related reactions (39%), pneumonia (31%), upper respiratory tract infection (57%), and diarrhea (26%). Serious adverse reactions occurring in more than 5% of patients included pneumonia and febrile neutropenia, which were reported in 25.3% and 12.3% of patients, respectively.[2]

Isatuximab has previously been granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA). Phase III clinical trials evaluating isatuximab in other combinations for patients with relapsed, refractory, or newly diagnosed multiple myeloma are still ongoing. Efficacy and safety of the antibody for the treatment of other hematologic malignancies and solid tumors is also being evaluated.[2]

**References**

1. U.S. Food & Drug Administration. FDA approves new therapy for patients with previously treated multiple myeloma. https://www.fda.gov/news-events/press-announcements/fda-approves-new-therapy-patients-previously-treated-multiple-myeloma. Published March 2, 2020. [Accessed March 3, 2020]

2. Sanofi Genzyme. FDA approves Sarclisa® (isatuximab-irfc) for patients with relapsed refractory multiple myeloma. https://www.sanofigenzyme.com/en/about-us/newsroom/2020/2020-03-02-02-14-00. Published March 2, 2020. [Accessed 03 March 2020]

3. Attal M. et al. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. Lancet. 2019 Dec 7; 394(10214):2096–2107. DOI: 10.1016/S0140-6736(19)32556-5