FDA Approves Darzalex (Daratumumab) for Multiple Myeloma

Darzalex in combination with lenalidomide and dexamethasone is for people who are ineligible for an autologous stem cell transplant.

June 27, 2019 By Food and Drug Administration (FDA)

On June 27, 2019, the Food and Drug Administration approved daratumumab (Darzalex, Janssen Biotech, Inc.) in combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Approval was based on MAIA (NCT02252172), an open-label, randomized (1:1), active-controlled phase 3 study, comparing dartumumab (16 mg/kg) in combination with lenalidomide and low-dose dexamethasone (DRd) to lenalidomide and low-dose dexamethasone (Rd), in 737 patients with newly diagnosed multiple myeloma who were ineligible for autologous stem cell transplant.

The trial demonstrated an improvement in progression-free survival (PFS) in the DRd arm compared with the Rd arm. The median PFS had not been reached in the DRd arm and was 31.9 months in the Rd arm (HR 0.56; 95% CI: 0.43, 0.73; $p<0.0001$). The median time to response was 1.05 months (range: 0.2 to 12.1 months) in the DRd group and 1.05 months (range: 0.3 to 15.3 months) in the Rd group. The median response duration had not been reached in the DRd group and was 34.7 months (95% CI: 30.8, not estimable) in the Rd group.

Daratumumab can cause severe and/or serious infusion reactions, including anaphylactic reactions. Approximately half of all patients in clinical trials experienced an infusion reaction. Patients should be pre-medicated with antihistamines, antipyretics and corticosteroids. Frequently monitor patients during the entire infusion is recommended.

In newly diagnosed multiple myeloma patients who received daratumumab in combination with lenalidomide and dexamethasone, the most frequent (≥20%) adverse reactions were infusion reactions, diarrhea, constipation, nausea, peripheral edema, fatigue, back pain, asthenia, pyrexia, upper respiratory tract infection, bronchitis, pneumonia, decreased appetite, muscle spasms, peripheral sensory neuropathy, dyspnea and cough.

The recommended daratumumab dose is 16 mg/kg actual body weight. View full prescribing information for drugs used in combination and schedule.

This application used the Real-Time Oncology Review. FDA granted this application priority review.

A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

This announcement was originally published on the Food and Drug Administration website.
