FDA Approves Darzalex for Transplant-Eligible Multiple Myeloma

The approval is based on data from CASSIOPEIA, an open-label, randomized, active-controlled phase 3 study.

October 1, 2019 By Food and Drug Administration (FDA)

On September 26, 2019, the Food and Drug Administration approved daratumumab (DARZALEX, Janssen) for adult patients with multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT).

Efficacy was investigated in CASSIOPEIA (NCT02541383), an open-label, randomized, active-controlled phase 3 study comparing induction and consolidation treatment with daratumumab 16 mg/kg in combination with bortezomib, thalidomide and dexamethasone (DVTd) to treatment with bortezomib, thalidomide and dexamethasone (VTd) in patients with newly diagnosed multiple myeloma eligible for ASCT.

Approval is based on data from CASSIOPEIA, including progression-free survival (PFS), stringent complete response (sCR) at 100 days post-ASCT, and CR rate at day 100 post-ASCT. The trial demonstrated an improvement in PFS in the DVTd arm as compared to the VTd arm; with a median follow up of 18.8 months, the median PFS had not been reached in either arm. Treatment with DVTd resulted in a reduction in the risk of progression or death by 53% compared to VTd alone (HR=0.47; 95% CI: 0.33, 0.67; $p<0.0001$).The sCR rate at Day 100 post-ASCT was 28.9% in the DVTd arm and 20.3% in the VTd arm.

In patients with newly diagnosed multiple myeloma who received daratumumab in combination with bortezomib, thalidomide and dexamethasone, the most frequent (≥20%) adverse reactions were infusion reactions, peripheral sensory neuropathy, constipation, asthenia, nausea, peripheral edema, neutropenia, thrombocytopenia, pyrexia and paresthesia. Adverse reactions that occurred with at least 5% greater frequency in the DVTd arm were infusion reactions, nausea, neutropenia, thrombocytopenia, lymphopenia and cough. There were no significant differences in the number or type of serious adverse events in the two treatment arms.

The recommended daratumumab dose is 16 mg/kg actual body weight.

View full prescribing information for DARZALEX.

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.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

Check out recent approvals at the OCE's podcast, Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.).

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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