Generic Name:
Daratumumab
Trade Name:
Darzalex
Company:
Janssen
Notes:

Janssen announced FDA approval of daratumumab in combination with lenalidomide and dexamethasone (Rd) for treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).

Approval was based on results from the Phase III MAIA (MMY3008) clinical study, which showed that daratumumab-Rd significantly reduced the risk of disease progression or death by 44% percent compared with treatment with Rd alone.

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.

Serious adverse reactions were pneumonia, bronchitis, and dehydration.

Medication Monitor Categories:
Supplemental Approvals