FDA approves Darzalex Faspro for treating multiple myeloma

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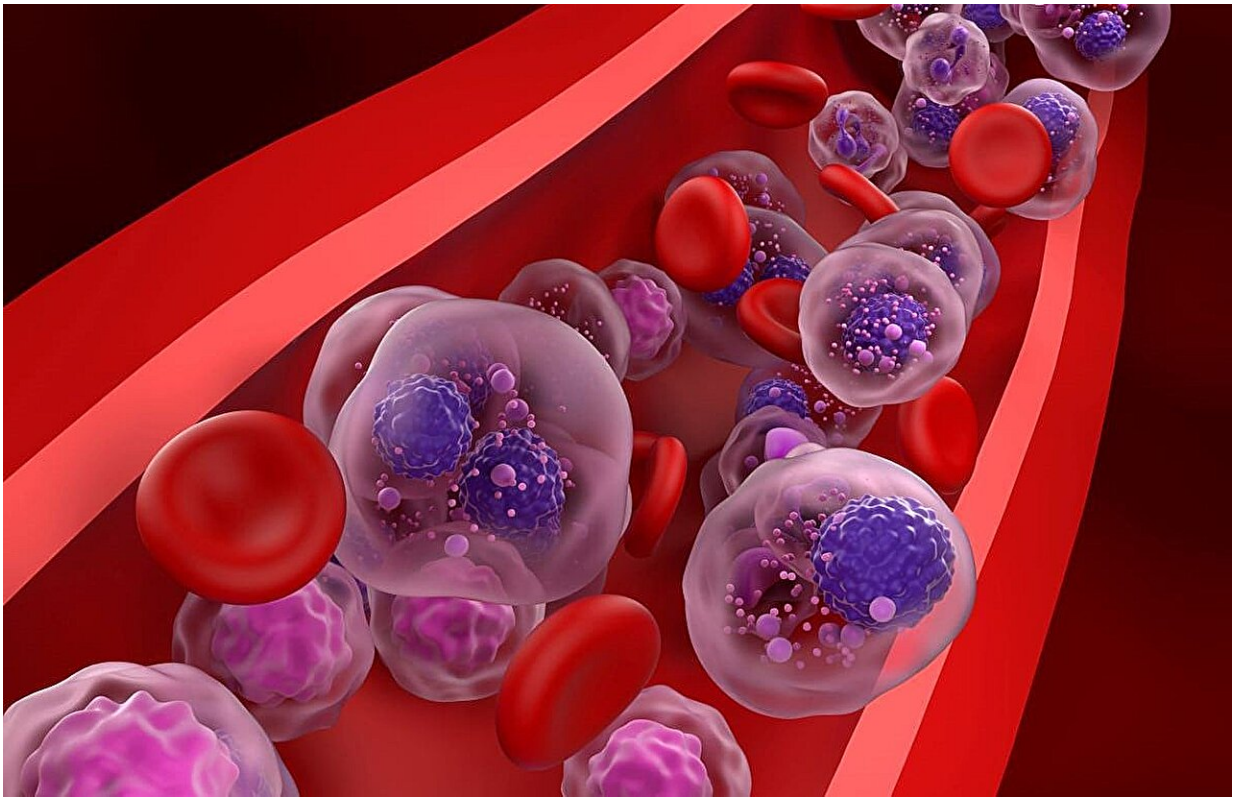

The U.S. Food and Drug Administration has approved Johnson & Johnson's Darzalex Faspro (daratumumab and hyaluronidase-fihj) in combination with bortezomib, lenalidomide, and dexamethasone (D-VRd) for induction and consolidation in patients with newly diagnosed

multiple myeloma (MM) who are eligible for an autologous stem cell transplant (ASCT).

The approval was based on a Phase III trial comparing the efficacy and safety of D-VRd during induction and consolidation versus VRd during induction and consolidation in patients with MM eligible for ASCT.

Findings showed significant improvement in the primary end point of progression-free survival (hazard ratio, 0.40). Compared with VRd (32.5 percent), minimal residual disease (MRD) negativity rates were 57.5 percent with D-VRd and MRD negativity rates in patients with complete response or better were 76.6 versus 58.5 percent.

The most common adverse reactions (≥20 percent) with D-VRd were peripheral neuropathy, fatigue, edema, pyrexia, upper respiratory infection, constipation, diarrhea, musculoskeletal pain, insomnia, and rash.

"Multiple myeloma has a highly varied clinical course among patients and in each individual patient, and there is a continued need for innovation and therapies that employ different targets and combinations to provide patients with treatment options at diagnosis and throughout the course of their disease," Amrita Y. Krishnan, M.D., from the Judy and Bernard Briskin Multiple Myeloma Center at City of Hope in Duarte, California, said in a statement.

"The efficacy data supporting this new quadruplet regimen, combined with its established safety and tolerability profile, provide compelling evidence that adding D-VRd upon initial diagnosis as compared to VRd can deepen responses and prolong remissions in the context of autologous stem cell transplantation."

More information: More Information