FDA approves cord blood stem cell product for blood cancer patients

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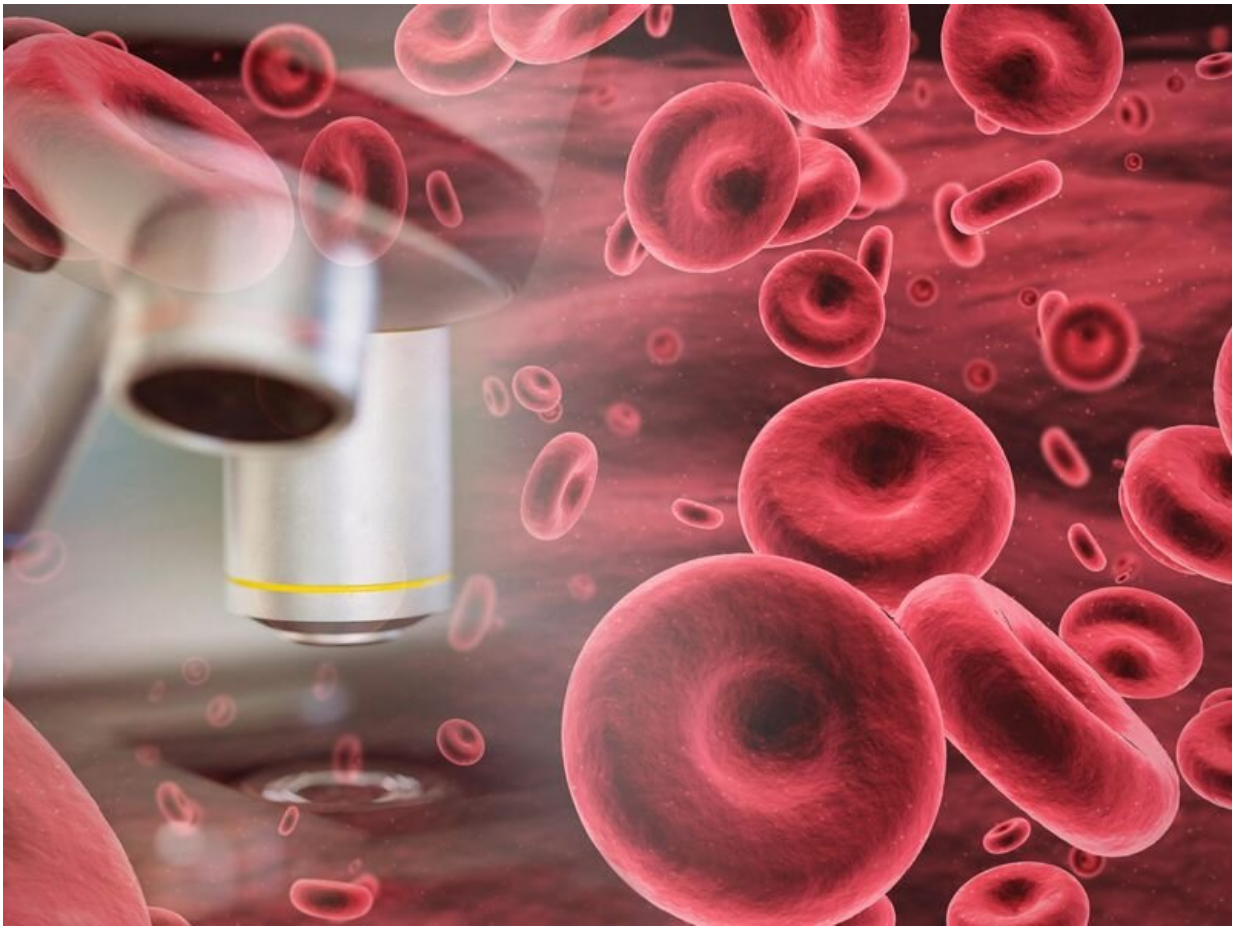

The U.S. Food and Drug Administration approved Omisirge (omidubicel-

onlv), a substantially modified allogeneic cord blood-based cell therapy, to cut the risk of infection in patients with blood cancer following a myeloablative treatment, such as radiation or chemotherapy.

Omisirge is administered as a single, patient-specific intravenous dose for blood cancer patients ≥12 years to hasten recovery of neutrophils. The treatment is composed of human donor stem cells from umbilical cord blood that are processed and cultured with nicotinamide.

The approval was based on data from a randomized, multicenter study comparing transplantation of Omisirge to transplantation of umbilical cord blood, in 125 patients with blood cancer (ages, 12 and 65 years). Among patients randomly assigned to Omisirge, 87 percent achieved neutrophil recovery with a median of 12 days following treatment versus 83 percent of participants randomly assigned to receive umbilical cord blood transplantation (median 22 days for neutrophil recovery). Within 100 days of transplantation, bacterial or fungal infections were seen in 39 percent of those receiving Omisirge versus 60 percent who received umbilical cord blood.

"Today's approval is an important advance in cell therapy treatment in patients with blood cancers," Peter Marks, M.D., Ph.D., director of the FDA Center for Biologics Evaluation and Research, said in a statement. "Hastening the return of the body's white blood cells can reduce the possibility of serious or overwhelming infection associated with stem cell transplantation."

More information: www.fda.gov/news-events/press- … -following-stem-cell