FDA approves sylvant for multicentric castleman's disease

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(HealthDay)—The U.S. Food and Drug Administration has approved Sylvant (siltuximab) to treat patients with multicentric Castleman's disease (MCD), according to a news release issued by the agency today.

The drug is given as an injection and works by blocking a protein that stimulates abnormal growth of immune cells. It is intended for patients with MCD who are not infected with HIV or human herpes virus 8 (HHV-8).

Sylvant was evaluated in 79 participants with MCD who were HIV and HHV-8 negative. The results showed that tumor response was experienced by participants receiving a combination of Sylvant and best supportive care, but not by participants receiving placebo and best supportive care. Itchy skin, weight gain, rash, increased levels of uric acid in the blood, and upper respiratory tract infection were found to be common side effects.

Sylvant was reviewed by the FDA under its priority review program, and the drug has been given orphan product designation as it is intended to treat a rare disease or condition.

"Sylvant is the first FDA-approved drug to treat patients with MCD," Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research, said in a statement. "Today's approval demonstrates the FDA's commitment to approving drugs for rare diseases."

Sylvant is marketed by Janssen Biotech Inc., based in Horsham, Pa.

More information: More Information