'BioSimilar' drug approved to treat certain types of anemia

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(HealthDay)—Retacrit (epoetin alfa-epbx) has been approved by the U.S. Food and Drug Administration as the first "biosimilar" to the anemia drugs Epogen and Procrit.

A biosimilar, derived from a living organism, has been proven to be "highly similar" to a product that's already been approved by the FDA. It's also been shown to have no "clinically meaningful differences" in its safety, purity and potency than the prior approved drugs, the agency explained Tuesday in a news release.

"Biosimilars can provide greater access to treatment options for patients, increasing competition and potentially lowering costs," said Leah Christi, Ph.D., director of the agency's Therapeutic Biologics and Biosimilars Staff.

Epogen/Procrit are approved to treat anemia caused by chronic kidney disease, chemotherapy or use of certain drugs to treat infection with HIV, the virus that causes AIDS.

Previously noted side effects of epoetin alfa include: high blood pressure , joint pain, muscle spasm, fever, dizziness, blood vessel blockage and respiratory infection, the FDA said.

As with Epogen/Procrit, Retacrit's label includes a boxed warning about increased risk of death, heart problems, stroke, tumor growth, high blood pressure, seizures and serious allergic reactions.

Retactrit is produced by Hospira Inc., a unit of New York City-based Pfizer.

More information: Learn more from the FDA.