

## Benlysta approved for children with lupus

29 April 2019



Benlysta plus standard therapy had a lower risk of a severe flare, the agency said.

The drug's label includes warnings for increased risk of death, serious infections, allergic-like reactions and depression. The drug should not be given at the same time as a person gets a live vaccine, the agency warned.

The <u>drug</u>'s most common side effects include nausea, diarrhea and fever. Given the medication's history for causing allergic-like reactions, <u>health</u> <u>professionals</u> are advised to pre-treat users with an antihistamine, the FDA said.

Benlysta is produced by GlaxoSmithKline, based in the United Kingdom.

More information: Visit the FDA to learn more.

(HealthDay)—The intravenous drug Benlysta (belimumab) has been approved by the U.S. Food and Drug Administration to treat children with lupus, a chronic disease that triggers inflammation and damages tissues and organs throughout the body.

Approved for adults since 2011, Benlysta is the first lupus treatment in the United States approved for children, the agency said in a news release.

"While there is no cure for lupus, treatment can help our youngest patients control their disease with the hope of improving their quality of life and lowering their risk of long-term organ damage and disability," said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research.

Though rare, childhood lupus typically is more serious than is lupus among adults. Children are at higher risk for developing serious organ damage and other complications, the FDA said.

Benlysta was clinically evaluated among 93 children with the disease. Those who received

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