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Gsk’s biologic treatment gets EC approval to treat children with lupus

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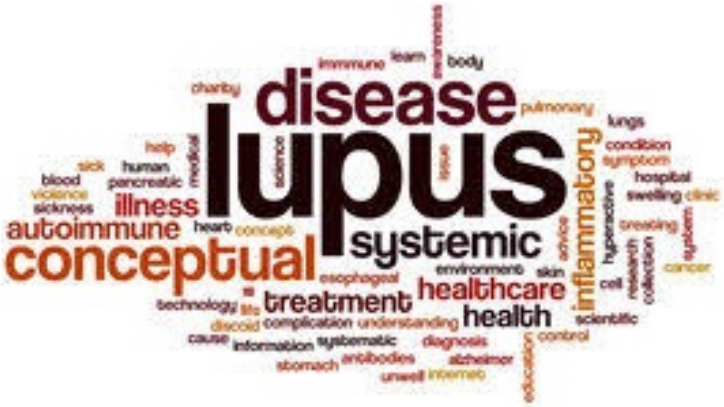
Intravenous Benlysta is the first biologic treatment to be approved for children with lupus in Europe



GlaxoSmithKline plc has announced that the European Commission has adopted a decision to extend to children five years and older, the existing adult indication for intravenous Benlysta (belimumab) as an add-on therapy in patients with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity.

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK said: “Children with lupus typically have more severe disease and earlier onset of organ damage than adults, but until now their treatment options have been limited. This approval means that for the first time in Europe these children can be treated with a biologic therapy specifically developed and approved for their disease.”

Alain Cornet, General Secretary of Lupus Europe, a charity supporting people with lupus in Europe, commented: “This decision is great news for the lupus community in Europe and particularly for young people affected and their supportive families, that so much need new therapeutic options. We are thankful to the many patients who, by taking part in clinical trials, made such progress possible.”

There are estimated to be between 3,000 and 6,000 children aged five to 17 years old with systemic lupus erythematosus in the European Union. In children this disease is associated with more rapid accrual of damage and has a higher degree of morbidity compared with systemic lupus erythematosus in adult populations.[2,3]

This approval by the European Commission follows recent approvals in the US and Japan, all supported by data from PLUTO, a post-approval commitment study.