



## Benlysta® (belimumab) – Expanded indication

- On April 26, 2019, the [FDA announced](#) the approval of [GlaxoSmithKline's Benlysta \(belimumab\)](#), for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.
  - The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.
  - Previously, Benlysta was only approved in adult patients.
- While childhood-onset SLE is rare, when diagnosed, it is generally more active in children and adolescents than adult patients, particularly in how it impacts organs such as the kidneys and central nervous system. As a result of the disease starting early in life, pediatric patients with SLE are at a higher risk for developing increased organ damage and complications from the disease as well as adverse events from the life-long treatments usually required.
- This is the first FDA approved treatment for pediatric patients with SLE.
- The approval of Benlysta's expanded indication was based on a double-blind study in 93 pediatric patients with a clinical diagnosis of SLE. Patients were randomized to Benlysta or placebo and all patients received background standard therapy. The primary efficacy endpoint was the SLE Responder Index (SRI-4) at week 52.
  - The proportion of patients achieving the primary endpoint was numerically higher with Benlysta plus standard therapy (53%) vs. placebo plus standard therapy (44%) (Odds Ratio 1.49; 95% CI: 0.64, 3.46).
  - In addition, Benlysta's safety and pharmacokinetic profiles in pediatric patients were consistent with those in adults with SLE.
- The recommended dosage of Benlysta in pediatric patients is 10 mg/kg at 2-week intervals intravenously (IV) for the first 3 doses and at 4-week intervals thereafter.
  - Prior to IV dosing, administering premedication should be considered for prophylaxis against infusion reactions and hypersensitivity reactions.
  - Refer to the Benlysta drug label for additional dosing recommendations.



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