Benlysta® (belimumab) – New indication

- On December 17, 2020, GlaxoSmithKline announced the FDA approval of Benlysta (belimumab), for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.
    - The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations.
- Benlysta is also approved for the treatment of patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.
- In lupus nephritis, SLE causes kidney inflammation and can lead to end-stage kidney disease, which requires kidney dialysis or a transplant.
- Benlysta is the first drug approved to treat SLE and active lupus nephritis.
- The approval of Benlysta for the new indication was based on a 104-week, randomized, double-blind, placebo-controlled study in 448 patients with active proliferative and/or membranous lupus nephritis. The primary efficacy endpoint was Primary Efficacy Renal Response (PERR) at week 104, defined as a response at week 100 confirmed by a repeat measurement at week 104 of the following parameters: urine protein:creatinine ratio 0.7 g/g and estimated glomerular filtration rate (eGFR) 60 mL/min/1.73 m^2 or no decrease in eGFR of > 20% from pre-flare value.
    - PERR was achieved in 32% and 43% of patients treated with placebo plus standard therapy vs. Benlysta plus standard therapy, respectively (Odds Ratio 1.6; 95% CI: 1.0, 2.3; p = 0.031).
    - The major secondary endpoints also showed significant improvement with Benlysta plus standard therapy vs. placebo plus standard therapy.
- The recommended intravenous (IV) dose of Benlysta for the treatment of lupus nephritis is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Premedication should be considered for prophylaxis against infusion reactions and hypersensitivity reactions.
- In patients initiating therapy with Benlysta for active lupus nephritis, the recommended subcutaneous (SC) dosage regimen is a 400-mg dose (two 200-mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter. A patient with lupus nephritis may transition from IV therapy to SC therapy any time after the patient completes the first 2 IV doses. If transitioning, administer the first SC dose of 200 mg 1 to 2 weeks after the last IV dose.

- It is recommended that the first SC injection of Benlysta should be under the supervision of a healthcare professional. The healthcare provider should provide proper training in SC technique and education about signs and symptoms of hypersensitivity reactions. A patient may self-inject or the patient caregiver may administer Benlysta SC after the healthcare provider determines it is appropriate.

- Refer to the Benlysta drug label for dosing for SLE.