Benlysta® (belimumab) – Expanded indication

- On July 27, 2022, GSK announced the FDA approval of Benlysta (belimumab), for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.
    - Benlysta was previously approved for this indication for adults only.
- Benlysta is also approved for the treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.
- The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in this situation.
- Use of Benlysta in pediatric patients with active lupus nephritis is based on the extrapolation of efficacy from the intravenous study in adults (n = 224) with active lupus nephritis, and supported by pharmacokinetic data from intravenous studies in adults (n = 224) with active lupus nephritis and from pediatric patients (n = 53) with SLE. Estimated belimumab exposures for pediatric patients were comparable to adults with active lupus nephritis.
- The recommended intravenous dosage of Benlysta for pediatric patients with lupus nephritis is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.
    - Benlysta should be administered by healthcare providers prepared to manage anaphylaxis.
    - Refer to the Benlysta drug label for dosing for its other uses.