Benlysta® (belimumab) – New formulation approval

- On July 21, 2017, GlaxoSmithKline announced the FDA approval of Benlysta (belimumab) injection, for subcutaneous (SC) use, for the treatment of adult patients 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 (IV) cyclophosphamide. Use of Benlysta is not recommended in these situations.
- Benlysta is also available as an injection for IV use and will continue to be available.
- The safety and efficacy of Benlysta injection for SC use was demonstrated in a placebo-controlled trial enrolling 836 patients with SLE for 52 weeks. The primary efficacy endpoint was the SLE responder index-4 (SRI-4) at week 52
    - The proportion of patients achieving an SRI-4 response was significantly higher in patients receiving Benlysta plus standard therapy vs. placebo plus standard therapy (61% vs. 48%, respectively; odds ratio = 1.7 [95% CI: 1.3, 2.3]; $p < 0.0006$).
- Contraindications with Benlysta include previous anaphylaxis to Benlysta.
- Other warnings and precautions of Benlysta include mortality, serious infections, hypersensitivity reactions, including anaphylaxis, infusion reactions, depression, malignancy, immunization, and concomitant use with other biologic therapies or IV cyclophosphamide.
- The most common adverse events (≥ 5%) with Benlysta use were nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in extremity, depression, migraine, pharyngitis, and injection site reactions (SC administration).
- The recommended dose of Benlysta injection for SC use is 200 mg once weekly.
    - It is recommended that the first SC injection of Benlysta should be under the supervision of a healthcare provider.
    - A patient may self-inject or the patient caregiver may administer Benlysta by SC injection after the healthcare provider determines it is appropriate.
- The recommended IV dosage regimen for Benlysta is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.
- GlaxoSmithKline plans to launch Benlysta injection for SC use in late August 2017. Benlysta for SC use will be available as a 200 mg/mL single-dose prefilled autoinjector and as a single-dose prefilled syringe.