## Epysqli® (eculizumab-aagh) – New biosimilar approval

- On July 22, 2024, Samsung Bioepis announced the FDA approval of Epysqli (eculizumab-aagh), biosimilar to AstraZeneca's Soliris® (eculizumab).
    - Epysqli is the second FDA-approved biosimilar to Soliris.
    - Amgen's Bkemv™ (eculizumab-aeeb) was the first biosimilar to Soliris. Bkemv also was granted interchangeability.
- Epysqli, Bkemv and Soliris share the following indications:
    - The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
    - The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- Epysqli, Bkemv and Soliris are *not* indicated for the treatment of patients with Shiga toxin *E. coli* related HUS.
- Soliris is also approved for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive and neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive.
- The approval of Epysqli is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Soliris.
- Epysqli, Bkemv and Soliris carry a boxed warning for serious meningococcal infections.
    - Because of the risk of serious meningococcal infections, Epysqli, Bkemv and Soliris are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Epysqli REMS, Bkemv REMS and Ultomiris® (ravulizumab -cwvz) and Soliris REMS, respectively.
- Epysqli is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.
- Additional warnings and precautions for Epysqli include other infections, monitoring disease manifestations after Epysqli discontinuation, thrombosis prevention and management, and infusion-related reactions.
- The most common adverse reactions (≥ 10% overall and greater than placebo) with Epysqli use in a PHN randomized trial were headache, nasopharyngitis, back pain, and nausea.
- The most common adverse reactions (≥ 20%) with Epysqli use in an aHUS single arm prospective trial were headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, and pyrexia.
- The recommended dosage of Epysqli in PHN in patients 18 years of age and older is 600 mg weekly as an intravenous (IV) infusion for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, then 900 mg every 2 weeks thereafter.

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- The recommended dosage of Epysqli in aHUS in patients 18 years of age and older is 900 mg as an IV infusion weekly for the first 4 weeks, followed by 1,200 mg for the fifth dose 1 week later, then 1,200 mg every 2 weeks thereafter.

- For patients less than 18 years of age for the treatment of aHUS, Epysqli should be administered based upon body weight, according to the schedule found in Epysqli's drug label.

- Samsung Bioepis' launch plans for Epysqli are pending. Epysqli will be available as a 300 mg/30 mL (10 mg/mL) solution in a single-dose vial.

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