Soliris® (eculizumab) – Expanded indication

- On February 28, 2025, the FDA approved AstraZeneca's Soliris (eculizumab), for the **treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 6 years of age and older who are anti-acetylcholine receptor (AChR) antibody positive**.
    - Solris was previously approved for this indication in adults only.
- Soliris is also approved for paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, and neuromyelitis optica spectrum disorder.
- The use of Soliris in pediatric patients with gMG is supported by evidence from an adequate and well-controlled trial in adults with additional pharmacokinetic and safety data in pediatric patients with gMG who are 12 years of age and older, and pharmacokinetic and safety data in other pediatric populations aged 6 to less than 12 years.
- Soliris carries a boxed warning for **serious meningococcal infections**.
    - Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Ultomiris and Soliris REMS.
- In pediatric patients with gMG, Soliris is administered as an **intravenous infusion based upon body weight**. Refer to the drug label for complete dosing and administration recommendations for this use and Soliris' other indications.