Uplizna® (inebilizumab-cdon) – New indication

- On April 3, 2025, Amgen announced the FDA approval of Uplizna (inebilizumab-cdon), for the **treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients**.
- Uplizna is also approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
- **Uplizna is the first FDA approved therapy for IgG4-RD**.
- IgG4-RD is a chronic, immune-mediated, fibroinflammatory disease which can affect different organs of the body. IgG4-RD can cause permanent organ damage with or without the presence of symptoms. The prevalence is estimated at 20,000 people in the U.S.
- The approval of Uplizna for the new indication was based on a randomized, double-blind, placebo-controlled study in 135 adult patients with IgG4-RD and confirmed history of organ involvement at any time in the course of disease. Patients received Uplizna or placebo. The primary endpoint was the time to first treated and adjudication committee-determined IgG4-RD flare.
    - **The time to the first IgG4-RD flare was significantly longer in the Uplizna group, compared with the placebo group. Uplizna reduced the risk of treated and adjudication committee-determined IgG4-RD flare by 87%, compared with placebo** (hazard ratio 0.13; $p < 0.0001$).
- The most common adverse reactions (≥ 10% of patients treated with Uplizna and greater than placebo) with Uplizna use were urinary tract infections and lymphopenia.
- The recommended dose of Uplizna is given as an intravenous (IV) infusion as follows:
    - Initial dose: 300 mg IV infusion followed 2 weeks later by a second 300 mg IV infusion
    - Subsequent doses (starting 6 months from the first infusion): single 300 mg IV infusion every 6 months.