Soliris® (eculizumab) – New indication

- On October 23, 2017, Alexion announced the FDA approval of Soliris (eculizumab) for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive.

- Soliris is also indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis; and for the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy.

    — Soliris is not indicated for the treatment of patients with Shiga toxin E. Coli related hemolytic uremic syndrome.

- Myasthenia gravis (MG) is a debilitating, chronic and progressive autoimmune neuromuscular disease that begins with weakness in the muscles of the eyes and eyelids, and often progresses to the more severe and generalized form, known as gMG, with weakness of the head, neck, trunk, limb and respiratory muscles.

    — In patients with anti-AchR antibody positive MG, the immune system produces antibodies against AchR, a receptor located on muscle cells. Patients with anti-AchR antibody-positive gMG who continue to suffer from disease symptoms despite therapy represent about 5 – 10% of all patients with MG.

- The efficacy of Soliris for the treatment of gMG was established in a placebo-controlled study of 125 patients with anti-AchR antibody positive gMG. The primary efficacy endpoint was a comparison of the change from baseline between treatment groups in the MG-specific Activities of Daily Living scale (MG-ADL) total score at week 26.

    — The Soliris group demonstrated a statistically significant greater decrease in MG-ADL total score vs. placebo (-4.2 vs. -2.3, p = 0.006).
    — Available data suggest that clinical response is usually achieved by 12 weeks of Soliris treatment.

- Soliris carries a boxed warning for serious meningococcal infections.

- The most frequently reported adverse reaction (≥ 10%) with Soliris use in the gMG placebo-controlled clinical trial was musculoskeletal pain.

- The recommended dosage regimen of Soliris for the treatment of gMG consists of 900 mg administered by intravenous infusion weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter.

- Refer to the Soliris drug label for dosing recommendations for all other indications.