Lokelma™ (sodium zirconium cyclosilicate) – New drug approval

- On May 18, 2018, AstraZeneca announced the FDA approval of Lokelma (sodium zirconium cyclosilicate), for the treatment of hyperkalemia in adults.
    - Lokelma should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.
- Hyperkalemia is a serious condition in which serum potassium levels are elevated. Patients with an increased risk of hyperkalemia include those with chronic kidney disease, heart failure, diabetes, and those taking renin-angiotensin-aldosterone system inhibitors.
- Lokelma is an insoluble, non-absorbed sodium zirconium silicate that acts as a highly-selective potassium-removing agent.
- The safety and efficacy of Lokelma were based on data from two double-blind, placebo-controlled studies and two open-label studies in adult patients with hyperkalemia.
    - The placebo-controlled studies demonstrated that patients treated with Lokelma had significant reductions in serum potassium levels vs. placebo-treated patients.
    - The two open-label studies showed that the treatment effect of Lokelma on serum potassium was maintained during continued therapy.
- Warnings and precautions of Lokelma include gastrointestinal adverse events in patients with motility disorders and edema.
- The most common adverse reactions with Lokelma were mild to moderate edema.
- The recommended starting dose of Lokelma is 10 g administered orally three times a day for up to 48 hours. For maintenance treatment, the recommended dose is 10 g once daily.
    - Lokelma is administered as a suspension in water.
    - During maintenance treatment, the dose may be adjusted at one-week intervals as needed (by 5 g daily) to obtain desired potassium target range.
    - Serum potassium should be monitored and the dose adjusted based on the serum potassium level and desired target range.
- AstraZeneca's plans to launch Lokelma are pending. Lokelma will be available as 5 g and 10 g packets for oral suspension.