Plenvu® (polyethylene glycol 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride) – New drug approval

- On May 7, 2018, Norgine announced the FDA approval of Plenvu (polyethylene glycol [PEG] 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride), for cleansing of the colon in preparation for colonoscopy in adults.

- Plenvu is an osmotic laxative and the first low volume (1 L) PEG-based bowel preparation.

- The efficacy and safety of Plenvu were evaluated in two randomized studies in adult patients scheduled to undergo a colonoscopy. In the NOCT study, 556 patients were randomized to Plenvu given as a two-day split dosing regimen vs. a trisulfate solution given as a two-day split dosing regimen. In the MORA study, 882 patients were randomized to Plenvu given as a two-day split dosing regimen or one-day dosing regimen vs. Moviprep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/ascorbic acid/sodium ascorbate) given as a two-day split dosing regimen.

    - The primary efficacy endpoint in both trials was the proportion of patients achieving overall bowel cleansing success.
    - In the NOCT study, Plenvu was shown to be non-inferior (NI) to the trisulfate solution comparator (overall bowel cleansing success: Plenvu 85.1% vs. trisulfate 85.0%; difference: 0.1% [97.5% one-sided lower CI: -8.2%]).
    - In the MORA study, both Plenvu dosing regimens were shown to be NI to Moviprep (overall bowel cleansing success: Plenvu two-day 92.0%, Plenvu one-day 89.1% vs. Moviprep 87.5%; difference for two-day: 4.5% [97.5% one-sided lower CI: -4.0%] and difference for one day: 1.6% [97.5% one-sided lower CI: -6.9%]).
    - NI was demonstrated if the difference between Plenvu and the comparator was above the predefined non-inferiority margin set at -10%.

- Plenvu is contraindicated in patients with gastrointestinal obstruction, bowel perforation, gastric retention, ileus, toxic megacolon, and hypersensitivity to any ingredient in Plenvu.

- Warnings and precautions of Plenvu include serious fluid and electrolyte abnormalities; cardiac arrhythmias; seizures; use in patients with renal impairment; colonic mucosal ulceration, ischemic colitis and ulcerative colitis; use in patients with significant gastrointestinal disease; aspiration; glucose-6-phosphate dehydrogenase deficiency; and risks in patients with phenylketonuria.

- The most common adverse reactions (> 2%) with Plenvu use were nausea, vomiting, dehydration, and abdominal pain/discomfort.

- Two doses of Plenvu are required for a complete preparation for colonoscopy, using a Two-Day or One-Day dosing regimen.

    - Two-Day: Dose 1 the evening before the colonoscopy (approximately 4 pm to 8 pm) and Dose 2 the next morning (approximately12 hours after the start of Dose 1).
    - One-Day: Dose 1 the morning of the colonoscopy (approximately 3 am to 7 am) and Dose 2 a minimum of 2 hours after the start of Dose 1.
    - Plenvu must be reconstituted in water prior to ingestion.
    - Additional clear liquids must be consumed after each dose of Plenvu in both dosing regimens.
    - Consult the Plenvu drug label for detailed dosing recommendations.

Continued . . .

- Norgine plans to have Salix Pharmaceuticals launch Plenvu in the second half of 2018. Plenvu will be available as a single-use carton containing three pouches labeled Dose 1, Dose 2 Pouch A, and Dose 2 Pouch B.