Glyrx-PF™ (glycopyrrolate) – New drug approval

- On July 11, 2018, the FDA announced the approval of Exela's Glyrx-PF (glycopyrrolate), for adult and pediatric patients in anesthesia and for adult patients in peptic ulcer as follows:
    - In anesthesia for reduction of salivary, tracheobronchial, and pharyngeal secretions, reduction of volume and acidity of gastric secretions, and blockade of cardiac inhibitory reflexes during induction of anesthesia and intubation; intraoperatively to counteract surgically or drug-induced or vagal reflex-associated arrhythmias; and for protection against peripheral muscarinic effects of cholinergic agents such as neostigmine and pyridostigmine given to reverse the neuromuscular blockade due to non-depolarizing agents.
    - As adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

- Glycopyrrolate is also available generically as an injectable solution and oral tablet, and as a branded oral solution (Cuvposa®), inhaled solution (Lonhala™ Magnair™), inhaled capsules (Seebri™ Neohaler®), inhaled combination capsules (Utibron™ Neohaler [indacaterol/glycopyrrolate]) and inhaled combination solution (Bevespi Aerosphere™ [glycopyrrolate/formeterol]).
    - Injectable solution carries the same indications as Glyrex-PF.
    - Oral tablets are indicated as adjunctive therapy in the treatment of peptic ulcer.
    - Cuvposa is indicated to reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling (eg, cerebral palsy).
    - Lonhala Magnair, Seebri Neohaler, Utibron Neohaler, and Bevespi Aerosphere are indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema.

- Glyrx-PF is contraindicated in peptic ulcer patients with glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, paralytic ileus, intestinal atony of the elderly or debilitated patient, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon, complicating ulcerative colitis, and myasthenia gravis; and in patients with known hypersensitivity to glycopyrrolate or any of its inactive ingredients.

- Warnings and precautions of Glyrx-PF include precipitation of acute glaucoma; drowsiness or blurred vision; heat prostration; intestinal obstruction; tachycardia; risk of use in patients with renal impairment, autonomic neuropathy, hepatic disease, ulcerative colitis, prostatic hypertrophy, or hiatal hernia; delayed gastric emptying/gastric stasis; and light sensitivity.

- The most common adverse reactions are related to anticholinergic pharmacology and may include dry mouth, urinary hesitancy and retention, blurred vision and photophobia due to mydriasis, cycloplegia, increased ocular tension, tachycardia, bradycardia, palpitation and decreased swelling.

- The recommended dosage of Glyrx-PF may be administered intramuscularly or intravenously with or without dilution.
    - Consult the Glyrex-PF drug label for specific dosing recommendations for each indication in adult and pediatric patients.

Continued . . .

- Exela’s launch plans for Glyrx-PF are pending. Glyrx-PF will be available as 0.2 mg/mL in 1 mL or 2 mL single-dose vials.