Sinuva™ (mometasone furoate) – New drug approval

- On December 11, 2017, Intersect ENT announced the FDA approval of Sinuva (mometasone furoate) sinus implant, for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

- Nasal polyps are inflammatory growths along the lining of nasal passages or sinuses that can cause nasal congestion, infections and loss of sense of smell. Approximately 635,000 Americans have had previous sinus surgery and continue to see their ENT physicians for treatment of recurring symptoms.

- The efficacy of Sinuva was primarily based on a placebo-controlled study of 300 patients, ≥ 18 years of age, with nasal polyps and a history of ethmoid sinus surgery. The co-primary efficacy endpoints were change from baseline to day 30 in nasal obstruction/ congestion score and change from baseline to day 90 in bilateral polyp grade.

    - Sinuva-treated patients experienced a statistically significant reduction in nasal obstruction/congestion score vs. placebo-treated patients (-0.80 vs. -0.56, respectively; difference: -0.23 [95% CI: -0.39, -0.06]).
    - Sinuva-treated patients experienced a statistically significant reduction in bilateral polyp grade vs. placebo-treated patients (-0.56 vs. -0.15, respectively; difference: -0.35 [95% CI: -0.60, -0.09]).

- Warnings and precautions of Sinuva include local effects, ocular effects, hypersensitivity reactions, immunosuppression, and hypercorticism and adrenal suppression.

- The most common adverse reactions (> 1%) with Sinuva use were bronchitis, nasopharyngitis, otitis media, headache, presyncope, asthma, and epistaxis.

- Sinuva is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. Sinuva may be left in the sinus to gradually release the corticosteroid over 90 days, and can be removed at day 90 or earlier at the physician's discretion using standard surgical instruments.

    - Sinuva is to be used by physicians trained in otolaryngology.
    - There are no studies evaluating repeat implantation of Sinuva.

- Intersect ENT plans to launch Sinuva in the second quarter of 2018. Sinuva will be available as a sterile, single-use, bioabsorbable implant, coated with a formulation containing 1,350 mcg mometasone furoate.