Lonhala™ Magnair™ (glycopyrrolate) – New drug approval

- On December 5, 2017, Sunovion announced the FDA approval of Lonhala Magnair (glycopyrrolate), for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

- COPD is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation. Symptoms of COPD include coughing, wheezing, shortness of breath, excess production of mucus in the lungs, the inability to breathe deeply and the feeling of being unable to breathe. Approximately 15.7 million adults in the U.S. have COPD.

- Lonhala Magnair is a long-acting muscarinic antagonist (LAMA) bronchodilator that helps the muscles around the airways in the lungs stay relaxed to prevent COPD symptoms. Lonhala Magnair is the first nebulized LAMA approved for COPD.

- The safety and efficacy of Lonhala Magnair were demonstrated in two 12-week, placebo-controlled studies (GOLDEN-3 and GOLDEN-4) enrolling 1,293 COPD patients and a 48-week, open-label, active-controlled study (GOLDEN-5) of 1,087 COPD patients. For the placebo-controlled studies, the primary endpoint was the change from baseline in trough forced expiratory volume in one second (FEV_1) at day 84 vs. placebo.

    - In GOLDEN-3, the change in FEV_1 was 0.089 for the Lonhala Magnair-treated patients vs. -0.008 for the placebo-treated patients (difference: 0.096 [95% CI: 0.059, 0.133]).
    - In GOLDEN-4, the change in FEV_1 was 0.092 for the Lonhala Magnair-treated patients vs. 0.011 for the placebo-treated patients (difference: 0.081 [95% CI: 0.042, 0.120]).
    - In GOLDEN-5, the overall treatment emergent adverse events incidences were similar for the Lonhala Magnair and Spiriva® HandiHaler® (tiotropium) groups over 48 weeks.

- Warnings and precautions of Lonhala Magnair include deterioration of disease and acute episodes, paradoxical bronchospasm, immediate hypersensitivity reactions, worsening of narrow-angle glaucoma, and worsening of urinary retention.

- The most common adverse reactions (≥ 2% and higher than placebo) with Lonhala Magnair use were dyspnea and urinary tract infection.

- The recommended dose of Lonhala Magnair is the inhalation of the contents of one Lonhala vial twice-daily (1 vial in the morning and 1 vial in the evening) using Magnair.

- Sunovion plans to launch Lonhala Magnair in early 2018. Lonhala Magnair will be available as an aqueous solution for inhalation in a unit-dose, single-use 1 mL vial containing 25 mcg of glycopyrrolate.