Yupelri™ (revefenacin) – New drug approval

- On November 9, 2018, Theravance Biopharma and Mylan announced the FDA approval Yupelri (revefenacin), for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

- COPD 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, and the inability to breathe deeply. Approximately 15.7 (6.4%) million adults in the U.S. have COPD and it is the third leading cause of death.

- Yupelri is a long-acting muscarinic antagonist (LAMA) bronchodilator. Yupelri is the first once-daily nebulized LAMA approved for COPD.

- The efficacy of Yupelri is based on two 12-week, placebo-controlled studies in 1,229 patients with moderate-to-severe COPD. The primary endpoint was change from baseline in trough forced expiratory volume in one second (FEV_1) at day 85.

    - In study 1, the least-square (LS) mean change in FEV_1 (mL) was 127 for the Yupelri-treated patients vs. -19 for the placebo-treated patients (difference: 146; 95% CI: 103.7, 188.8).
    - In study 2, the LS mean change in FEV_1 (mL) was 102 for the Yupelri-treated patients vs. -45 for the placebo-treated patients (difference: 147; 95% CI: 97.0, 197.1).

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

- The most common adverse reactions (≥ 2% and more common than placebo) include cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain.

- The recommended dose of Yupelri inhalation solution is one 175 mcg unit-dose vial administered once daily by nebulizer using a mouthpiece.

    - Yupelri should be administered by the inhaled route via a standard jet nebulizer connected to an air compressor.
    - Safety and efficacy have been established in clinical trials when administered using the PARI LC® Sprint nebulizer with a mouthpiece and the PARI Trek® S compressor. The safety and efficacy delivered from non-compressor based nebulizer systems have not been established.

- Theravance Biopharma and Mylan plan to launch Yupelri before the end of the year. Yupelri will be available as a 175 mcg/3 mL inhalation solution in unit-dose vials