Tyvaso DPI™ (treprostinil) – New drug approval

- On May 24, 2022, United Therapeutics announced the FDA approval of Tyvaso DPI (treprostinil), for the treatment of:
    - Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.
    - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.
- PAH is life-threatening high blood pressure in the arteries of the lungs, affecting the ability of the heart and lungs to work properly in afflicted patients. PAH affects an estimated 45,000 patients in the U.S.
- ILD is a group of lung diseases that are characterized by marked scarring or fibrosis of the bronchioles and alveolar sacs within the lungs. Pulmonary hypertension frequently complicates the course of patients with ILD and is associated with worse functional status. PH-ILD is estimated to affect at least 15% of patients with ILD (approximately 30,000 PH-ILD patients) and may affect up to 86% of patients with more severe ILD.
- Tyvaso DPI is a new formulation and inhalation device for inhaled treprostinil and is the only dry powder inhaler approved for use in PAH and PH-ILD.
    - Treprostinil is also available as a nebulizer solution (Tyvaso®) for the same indications.
- FDA approval of Tyvaso DPI was supported by data from BREEZE, an open label, safety and tolerability study of 51 PAH patients on a stable regimen of Tyvaso inhalation solution who were transitioned to Tyvaso DPI.
- Warnings and precautions for Tyvaso DPI include risk of symptomatic hypotension, risk of bleeding, effect of other drugs on treprostinil, and bronchospasm.
- The most common adverse reactions (≥ 4%) with Tyvaso DPI use were cough, headache, throat irritation/pharyngolaryngeal pain, nausea, flushing, dyspnea, and syncope.
- The recommended initial dose of Tyvaso DPI in adults is one 16 mcg cartridge per treatment session, 4 times daily. The dosage should be increased by an additional 16 mcg per treatment session at approximately 1- to 2-week intervals. The target maintenance dosage is usually 48 mcg to 64 mcg per session.
- United Therapeutics plans to launch Tyvaso DPI in June 2022. Tyvaso DPI will be available as a 16 mcg, 32 mcg, 48 mcg, or 64 mcg dry powder formulation.