Uptravi® (selexipag) injection – New formulation approval

- On July 30, 2021, Janssen announced the FDA approval of Uptravi (selexipag) injection, for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

- Uptravi was previously approved as an oral tablet.

    — Uptravi injection should be used in patients who are temporarily unable to take oral therapy.

- The approval of Uptravi injection was based upon the findings from an open-label single sequence cross-over study assessing the safety, tolerability, and pharmacokinetics of temporarily switching between Uptravi tablets and Uptravi injection in 20 patients.

- Uptravi is contraindicated in patients with concomitant use of strong inhibitors of CYP2C8.

- A warning and precaution for Uptravi is pulmonary edema with pulmonary veno-occlusive disease.

- Adverse reactions occurring more frequently (≥ 5%) with Uptravi use vs. placebo were headache, diarrhea, jaw pain, nausea, myalgia, vomiting, pain in extremity, and flushing.

- Uptravi for injection is administered twice daily by intravenous infusion at a dose that corresponds to the patient's current dose of Uptravi tablets. Uptravi for injection should be administered as an 80-minute intravenous infusion.

    — Refer to the Uptravi drug label for complete dosing and administration recommendations for the injection and for the oral tablet formulation.

- Janssen's launch plans for Uptravi injection are pending. Uptravi injection will be available as a 1,800 mcg lyophilized powder in a single-dose vial for reconstitution and dilution.