Liqrev® (sildenafil) – New drug approval

- On April 28, 2023, the FDA approved CMP Pharma's Liqrev (sildenafil) oral suspension, for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

- Sildenafil is available generically as oral 25 mg, 50 mg and 100 mg tablets, oral 20 mg tablet, oral powder for suspension, and injection.

    - Sildenafil oral 25 mg, 50 mg, and 100 mg tablets are approved for the treatment of erectile dysfunction.
    - Sildenafil oral 20 mg tablet, oral powder for suspension, and injection carry the same indication as Liqrev.
    - Revatio® (sildenafil) brand product carries the indication for PAH treatment in pediatric patients 1 to 17 years of age.

- The approval of Liqrev was based on efficacy trials conducted with Revatio.

- Liqrev is contraindicated in patients with concomitant use of organic nitrates in any form, either regularly or intermittently, because of the greater risk of hypotension; concomitant use of Adempas® (riociguat). Phosphodiesterase-5 (PDE-5) inhibitors, including sildenafil, may potentiate the hypotensive effects of Adempas; and known hypersensitivity to sildenafil or any component of the oral suspension.

- Warnings and precautions for Liqrev include hypotension, worsening pulmonary vascular occlusive disease, epistaxis, visual loss, hearing loss, combination with other PDE-5 inhibitors, priapism, and vaso-occlusive crisis in patients with pulmonary hypertension secondary to sickle cell disease.

- The most common adverse reactions with Liqrev use were headache, dyspepsia, flushing, pain in limb, myalgia, back pain and diarrhea.

- The recommended dosage of Liqrev is 20 mg orally three times a day.

- CMP Pharma's launch plans for Liqrev are pending. Liqrev will be available as a 10 mg/mL oral suspension.