Rapiblyk (landiolol) – New drug approval

- On November 22, 2024, the FDA approved AOP Orphan Pharmaceuticals' Rapiblyk (landiolol), for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.

- Rapiblyk is a beta adrenergic blocker.

- The efficacy of Rapiblyk was established in five randomized, double-blind, placebo-controlled studies in 317 adults with supraventricular tachycardia who were treated with landiolol.

    — Landiolol decreased heart rate in 40% to 90% of treated patients within about 10 minutes, compared to 0% to 11% of patients who received placebo; heart rate decrease was defined as a > 20% decrease in heart rate or a heart rate < 100 bpm or at least intermittent cessation of the arrhythmia.

- Rapiblyk is contraindicated in patients with:

    — Severe sinus bradycardia, sick sinus syndrome, heart block greater than first degree
    — Decompensated heart failure
    — Cardiogenic shock
    — Pulmonary hypertension
    — Hypersensitivity reactions, including anaphylaxis, to landiolol or any of the inactive ingredients.

- Warnings and precautions for Rapiblyk include hypotension; bradycardia; cardiac failure; reactive airways disease; use in patients with diabetes mellitus and hypoglycemia; infusion site reactions; use in patients with Prinzmetal's angina; use in patients with pheochromocytoma; use in patients with peripheral circulatory disorders; abrupt discontinuation of Rapiblyk injection; hyperkalemia; use in patients with metabolic acidosis; use in patients with hyperthyroidism; and use in patients at risk of severe acute hypersensitivity reactions.

- The most common adverse reaction with Rapiblyk use was hypotension.

- Rapiblyk is administered as a continuous intravenous infusion, titrating as needed for heart rate control (refer to the drug label for complete dosing recommendations). There are limited data beyond 24 hours of use.

- AOP Orphan Pharmaceuticals' launch plans for Rapiblyk are pending. Rapiblyk will be available as a 280 mg lyophilized powder in a single-dose vial.