Tryvio™ (aprocitentan) – New drug approval

- On March 20, 2024, Idorsia announced the FDA approval of Tryvio (aprocitentan), in combination with other antihypertensive drugs, for the treatment of hypertension, to lower blood pressure in adult patients who are not adequately controlled on other drugs.

- Tryvio is the first endothelin receptor antagonist approved for the treatment of hypertension.

- The efficacy of Tryvio was established in PRECISION, a multipart study in adults with systolic blood pressure (SBP) ≥140 mmHg who were prescribed at least three antihypertensive medications. Following a 4-week placebo run-in period, 730 patients were randomized equally to aprocitentan at either 12.5 mg, 25 mg, or placebo once daily during the initial 4-week double-blind treatment period. The primary endpoint was the change in sitting SBP from baseline to week 4.

    - The least squares mean change in sitting SBP was -15.4 mmHg with Tryvio 12.5 mg vs. -11.6 mmHg with placebo (difference -3.8, 97.5% CI: -6.8, -0.8; p = 0.0043).
    - Tryvio is not approved for use at a 25 mg dose. The 25 mg dose has not demonstrated a meaningful improvement in blood pressure reduction as compared to the 12.5 mg dose and had an increased risk of edema/fluid retention.

- Tryvio carries a boxed warning for embryo-fetal toxicity.

    - Tryvio is only available through a restricted distribution program called the Tryvio REMS.

- Tryvio is contraindicated in pregnancy and in patients who are hypersensitive to aprocitentan or any of its excipients.

- Additional warnings and precautions for Tryvio include hepatotoxicity; fluid retention; decreased hemoglobin; and decreased sperm counts.

- The most common adverse reactions (more frequent than placebo and ≥ 2% in Tryvio-treated patients) with Tryvio use were edema/fluid retention and anemia.

- The recommended dose of Tryvio is 12.5 mg orally once daily.

- Idorsia plans to launch Tryvio in the second half of 2024. Tryvio will be available as a 12.5 mg tablet.