

Tryvio[™] (aprocitentan) – New drug approval

- On March 20, 2024, <u>Idorsia announced</u> the FDA approval of <u>Tryvio (aprocitentan)</u>, 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.



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