

# Media Release August 19, 2025

# TRYVIO™ (aprocitentan) now included in ACC/AHA Clinical Practice Guidelines for the treatment of hypertension

- The updated recommendations now include TRYVIO™ (aprocitentan) the first and only hypertension treatment targeting the endothelin pathway.
- Endothelin is upregulated in hypertension and is a fundamental mediator in patients whose hypertension is difficult-to-control.
- Hypertension remains a major global health issue, and the number one modifiable risk factor of early morbidity/mortality.

# Allschwil, Switzerland & Radnor, Pennsylvania – August 19, 2025

Idorsia Ltd (SIX: IDIA) announces that its novel dual endothelin receptor antagonist (ERA), TRYVIO™ (aprocitentan), has been included in the new comprehensive clinical practice guidelines for the management of systemic hypertension, published by the American College of Cardiology (ACC) and the American Heart Association (AHA) Joint Committee. The updated recommendations now list TRYVIO as a therapy that may be added for adults with difficult-to-control hypertension, including resistant hypertension. TRYVIO is the first systemic hypertension treatment to target a new pathway in over 30 years and the only new medicine to be included in the updated guidelines.

Despite progress in improving patient outcomes, hypertension remains a major global health issue, and the number one modifiable risk factor of early morbidity/mortality, affecting an estimated 50% of adults in the US, with 50% of those patients not well controlled despite being on medication.

TRYVIO is indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. The recommended dosage of TRYVIO is 12.5 mg orally once daily, with or without food. TRYVIO is ideally positioned to treat patients with hypertension and chronic kidney disease (CKD), as the label indicates use in patients with eGFR as low as 15 mL/min. TRYVIO's blood pressure lowering effect was also consistent among subgroups defined by age, sex, race, BMI, baseline UACR, and medical history of diabetes.

# Srishti Gupta, MD, Chief Executive Officer of Idorsia, commented:

"Idorsia is grateful to the medical community and the joint guidelines committee for recognizing TRYVIO as an important option for patients with difficult-to-control hypertension. The clinical evidence from the development program has demonstrated that targeting the endothelin pathway in hypertension with TRYVIO can help address a critical unmet medical need. The TRYVIO approval and inclusion in the updated clinical practice guidelines are a testament to our commitment to discover and develop innovative medicines that improve patient outcomes."

### **AHA Hypertension Scientific Sessions**

The new guidelines will be discussed at the upcoming American Heart Association's (AHA) Hypertension Scientific Sessions held September 4-7, 2025, in Baltimore, MD.



In addition, Idorsia will present two scientific posters at the congress. One poster presents post-hoc analysis demonstrating that aprocitentan provided fast blood pressure control and a substantial UACR reduction which were both sustained until Week 36 in patients with grade 2 hypertension (defined as systolic blood pressure 160 to 179 mmHg) at baseline. The other poster presents post-hoc analysis in patients with isolated systolic hypertension-like characteristics at baseline, showing that aprocitentan substantially reduced systolic blood pressure while maintaining diastolic blood pressure above 70 mmHg to achieve clinically optimal values associated with minimal cardiovascular risk.

### US Prix Galien 2025 nominee

The Galien Foundation, the premier global institution dedicated to honoring innovators in life sciences, recently <u>announced</u> that TRYVIO has been nominated for the 2025 Prix Galien USA Awards in the category of "Best Pharmaceutical Product".

# About the ACC/AHA Guidelines

The American College of Cardiology and the American Heart Association published updated comprehensive clinical practice guidelines for the management of high blood pressure, focusing on evidence-based practices. The ACC and the AHA regularly publish guidelines and scientific statements, which are developed by volunteer scientists and healthcare professionals. The guidelines are based on the latest research and are rigorously reviewed to ensure that they reflect the current best practices in cardiovascular health.

## About aprocitentan

Aprocitentan is Idorsia's once-daily, orally active, dual endothelin receptor antagonist, which inhibits the binding of ET-1 to ETA and ETB receptors. Aprocitentan is approved as TRYVIO™ in the US for the treatment of systemic hypertension in combination with other antihypertensives and has been commercially available since October 2024. Aprocitentan is approved as JERAYGO™ for the treatment of resistant hypertension in combination with other antihypertensives in the European Union and the UK and marketing authorization applications are under review in Canada, and Switzerland.

For more information see the TRYVIO Full Prescribing Information including BOXED Warning (Pl and Medication Guide).

# Important Safety Information

What is the most important information I should know about TRYVIO? TRYVIO may cause serious side effects, including:

# Serious birth defects.

- TRYVIO may cause serious birth defects if taken during pregnancy.
- Females who can become pregnant should not be pregnant when they start taking TRYVIO or become pregnant during treatment with TRYVIO or for 1 month after stopping treatment with TRYVIO.
- Females who can become pregnant should have a negative pregnancy test before starting treatment with TRYVIO.
- Females who can become pregnant are females who:
  - have entered puberty, even if they have not started their menstrual period, and
  - have a uterus, and
  - have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.
- Females who cannot become pregnant are females who:
  - have not yet entered puberty, or
  - do not have a uterus, or



- have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, or
- are infertile for other medical reasons and this infertility is permanent and cannot be reversed.
- Females who can become pregnant should use effective birth control during treatment with TRYVIO, and for 1 month after stopping TRYVIO because the medicine may still be in your body.
  - Talk with your healthcare provider or gynecologist (a healthcare provider who specializes in female reproduction) to find out about options for effective birth control that you may use to prevent pregnancy during treatment with TRYVIO.
  - If you decide that you want to change the form of birth control that you use, talk with your healthcare provider or gynecologist to be sure that you choose another acceptable form of birth control.
- **Do not have unprotected sex.** Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your healthcare provider may talk with you about using emergency birth control.
- Tell your healthcare provider right away if you miss a menstrual period or you think you might be pregnant.

# Who should not take TRYVIO?

# Do not take TRYVIO if you are:

- · Pregnant or currently trying to become pregnant.
- allergic to aprocitentan or any of the ingredients in TRYVIO.

# Before taking TRYVIO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have heart failure
- have anemia
- have kidney problems or get dialysis
- are pregnant or plan to become pregnant during treatment with TRYVIO. TRYVIO can cause serious birth defects.
- are breastfeeding or plan to breastfeed. It is not known if TRYVIO passes into your breastmilk. Do
  not breastfeed if you take TRYVIO. Talk to your healthcare provider about the best way to feed
  your baby if you take TRYVIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

# What are the possible side effects of TRYVIO? TRYVIO may cause serious side effects, including:

- · Serious birth defects.
- **Liver problems.** TRYVIO may cause liver problems. Your healthcare provider should do blood tests to check your liver before starting treatment and as needed during treatment with TRYVIO. Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with TRYVIO:
  - nausea or vomiting
  - yellowing of your skin or whites of your eyes
  - pain in the upper right stomach
  - dark urine
  - tiredness
  - fever



- loss of appetite
- itching
- Fluid retention. Fluid retention and swelling are common during treatment with TRYVIO and can
  be serious. Tell your healthcare provider right away if you have any unusual weight gain, trouble
  breathing, or swelling of your ankles or legs. Your healthcare provider may treat you with other
  medicines (diuretics) if you develop fluid retention or swelling.
- Low red blood cell levels (anemia). Anemia is common during treatment with TRYVIO and can be serious. Your healthcare provider will do blood tests to check your red blood cells before starting and as needed during treatment with TRYVIO.
- Decreased sperm count. TRYVIO may cause decreased sperm counts in males and may affect the ability to father a child. Tell your healthcare provider if being able to have children is important to you.

Your healthcare provider may stop treatment with TRYVIO if you develop certain side effects. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of TRYVIO. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

#### Notes to the editor

#### **About Idorsia**

The purpose of Idorsia is to challenge accepted medical paradigms, answering the questions that matter most. To achieve this, we will discover, develop, and commercialize transformative medicines – either with in-house capabilities or together with partners – and evolve Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech hub – Idorsia has a highly experienced team of dedicated professionals, covering all disciplines from bench to bedside; QUVIVIQ™ (daridorexant), a different kind of insomnia treatment with the potential to revolutionize this mounting public health concern; strong partners to maximize the value of our portfolio; a promising in-house development pipeline; and a specialized drug discovery engine focused on small-molecule drugs that can change the treatment paradigm for many patients. Idorsia is listed on the SIX Swiss Exchange (ticker symbol: IDIA).

# For further information, please contact:

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