Media Release
September 19, 2025

Idorsia's JERAYGO (aprocitentan) approved in Switzerland for the treatment of resistant hypertension

- Idorsia receives approval from Swissmedic for JERAYGO™ (aprocitentan) as the first and only endothelin receptor antagonist (ERA) for the treatment of resistant hypertension.
- JERAYGO is a new oral antihypertensive therapy – the first systemic hypertension treatment to target a new pathway in over 30 years.

Allschwil, Switzerland – September 19, 2025
Idorsia Ltd (SIX: IDIA) announces that Swissmedic has granted marketing authorization for JERAYGO™ (aprocitentan) for the treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products.[1] The recommended dose is 12.5 mg orally once daily. The dose can be increased to 25 mg once daily for patients tolerating the 12.5 mg dose and in need of tighter blood pressure (BP) control.[1]

Hypertension remains a leading global health challenge and the number one modifiable risk factor for early morbidity and mortality. Despite advances in treatment, many patients still struggle with uncontrolled blood pressure, leaving them at significantly higher risk of heart attack, stroke, kidney failure, and premature death.

Approximately 10% of hypertensive patients have resistant hypertension[3,4] – defined by uncontrolled blood pressure despite receiving at least three antihypertensive medications from different classes, at optimal doses – underscoring the urgent need for more effective therapies.

Srishti Gupta, MD, Chief Executive Officer of Idorsia, commented:
"JERAYGO is the first and only hypertension treatment to target the endothelin pathway, a fundamental yet previously unaddressed driver of disease onset, progression, and complications. This breakthrough reflects nearly 30 years of research at our Swiss laboratories and represents Idorsia's second product approval in our home country. JERAYGO has demonstrated rapid, durable, and clinically significant double-digit blood pressure reduction across a broad spectrum of challenging patient populations, including those with obesity, chronic kidney disease, or type 2 diabetes. I am incredibly proud of our team for achieving this milestone."

Idorsia is engaged in discussions with potential partners to make JERAYGO available to patients across Switzerland and Europe.

For more information on the marketing authorization of JERAYGO in Switzerland, please refer to the Patient Information and Information for Healthcare Professionals.

Notes to the editor

About the Phase 3 PRECISION study[1,5]
The efficacy of aprocitentan was evaluated in one randomized, double-blind (DB), placebo-controlled Phase 3 multicenter study. Patients with uncontrolled blood pressure (systolic blood pressure [SBP] ≥140 mmHg) despite the use of at least three antihypertensive medicinal products and following exclusion of pseudo-resistant hypertension (e.g., white coat effect, inappropriate blood pressure measurement, secondary causes of hypertension) were considered to have resistant hypertension. The patients were switched to standardized background antihypertensive therapy consisting of an angiotensin

receptor blocker (valsartan 160 mg), a calcium channel blocker (amlodipine 5 or 10 mg), and a diuretic (hydrochlorothiazide 25 mg) throughout the study. Patients with concomitant use of beta-blockers continued this treatment throughout the study, in addition to the standardized background antihypertensive therapy and study treatment. A total of 730 patients received either aprocitentan 12.5 mg, aprocitentan 25 mg, or placebo once daily during the initial 4-week DB treatment (part 1). Thereafter, patients received aprocitentan 25 mg once daily during the 32-week single-blind treatment (part 2). At the end of the 32 weeks, patients were re-randomized to receive either aprocitentan 25 mg or placebo, once daily, during the 12-week double-blind withdrawal (DB-WD) treatment (part 3).

The primary efficacy endpoint was the change in sitting SBP (SiSBP) from baseline to Week 4 during DB treatment (part 1), measured at trough by unattended automated office blood pressure (uAOBP). The key secondary endpoint was the change in SiSBP measured at trough by uAOBP from DB-WD baseline (Week 36) to Week 40 (part 3).

Patients had a mean age of 61.7 years (range 24 to 84 years; 34.1% were ≥ 65 and < 75 years; 9.9% were ≥ 75 years) and 59.5% were male. Patients were White (82.9%), African American (11.2%) or Asian (5.2%). The mean body weight was 97.6 kg (range 46 to 196 kg) and mean BMI was 33.7 kg/m2 (range 18 to 64 kg/m2). Patients had a medical history of type 2 diabetes mellitus (54.1%), ischemic heart disease (30.8%), central nervous system vascular disorders (23.0%), chronic kidney disease stages 3 and 4 (22.2%; 19.3% of patients had eGFR 30–59 mL/min/1.73 m2 and 2.9% had eGFR 15–29 mL/min/1.73 m2), congestive heart failure (19.6%), and sleep apnea syndrome (14.1%). 63.0% of patients had four or more antihypertensive medicinal products.

Key PRECISION findings[1,5]

Doses of aprocitentan 12.5 and 25 mg showed a statistically significant reduction vs placebo on SiSBP at Week 4. The treatment effect was consistent for sitting diastolic blood pressure (SiDBP). The persistence of the BP-lowering effect of aprocitentan was shown in DB-WD treatment (part 3). In patients re-randomized to placebo, the mean SiSBP increased, whereas in patients re-randomized to aprocitentan 25 mg the mean effect on SiSBP was stable, resulting in a statistically significant difference. The treatment effect was consistent for SiDBP. The effect was also consistent across SBP and DBP measured by ambulatory BP monitoring (ABPM) and assessed as daytime, night-time, and 24h periods at Week 4 and Week 40. A substantial proportion (i.e., at least 90%) of the BP-lowering effect was observed within the first two weeks of treatment with aprocitentan. The effect of aprocitentan was consistent across subgroups of age (including patients ≥ 75 years), sex, race (including patients with Black or African American origin), BMI, baseline urine albumin-to-creatinine ratio (UACR), baseline eGFR and medical history of diabetes.

The most frequently reported adverse reactions with aprocitentan were edema/fluid retention (mostly peripheral edema) (9.1%, 12.5 mg; 18.4%, 25 mg) and hemoglobin decreased (3.7%, 12.5 mg; 1.2%, 25 mg).

JERAYGO is contraindicated for use in women who are pregnant, breast-feeding, in women of childbearing potential who are not using reliable contraception, patients with severe hepatic impairment, and in patients with hypersensitivity to the active substance or to any of the excipients.

About aprocitentan

Aprocitentan is Idorsia's once-daily, orally active, dual endothelin receptor antagonist, which inhibits the binding of ET-1 to ET_A and ET_B 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 at least three antihypertensives in the European Union, the UK, and Switzerland, and a marketing authorization application is under review in Canada.

Idorsia Pharmaceuticals Ltd has transferred its rights for aprocitentan (including JERAYGO™) to Idorsia Investments SARL to allow the repayment of newly created notes issued in connection with the repurchase offer completed in August 2025. More details on the transfer can be found in the press release issued on May 21, 2025 and on the exchange offer in the press release issued on August 27, 2025.

References

1. JERAYGO™ Information for Healthcare Professionals. 2025.
2. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. Lancet 2021; 398:957-80.
3. Noubiap JJ, et al. Global prevalence of resistant hypertension: a meta-analysis of data from 3·2 million patients. Heart 2019; 105: 98–105.
4. Williams B, et al. 2018 ESC/ESH guidelines for the management of arterial hypertension. Eur Heart J 2018; 39: 3021–104.
5. Schlaich MP, et al. A randomized controlled trial of the dual endothelin antagonist aprocitentan for resistant hypertension. The Lancet, 2022; Dec 3;400(10367):1927-1937.

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:
Investor & Media Relations
Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil
+41 58 844 10 10
investor.relations@idorsia.com - media.relations@idorsia.com - www.idorsia.com

The above information contains certain "forward-looking statements", relating to the company's business, which can be identified by the use of forward-looking terminology such as “intend”, "estimates", "believes", "expects", "may", "are expected to", "will", "will continue", "should", "would be", "seeks", "pending" or "anticipates" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the company's investment and research and development programs, business development activities and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company's existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.