Media Release
April 9, 2025

US FDA approves an updated label for TRYVIO (aprocitentan) removing the REMS requirement

Allschwil, Switzerland – April 9, 2025
Idorsia Ltd (SIX: IDIA) today announced that the US Food & Drug Administration (FDA), after having released TRYVIO from its REMS (Risk Evaluation and Mitigation Strategy) requirement (announced on March 17, 2025), has now approved the updated label for TRYVIO™ (aprocitentan). TRYVIO is Idorsia's dual endothelin receptor antagonist (ERA) indicated for the treatment of systemic hypertension in combination with other antihypertensives to lower blood pressure in patients who are not adequately controlled on other drugs. The FDA determined that a REMS was no longer necessary to ensure the benefits of TRYVIO outweigh the risk of embryo-fetal toxicity and that labeling is sufficient for conveying the safety information.

Michael Moye, President and General Manager of Idorsia US, commented: "The fact that the FDA has expedited the approval of the updated TRYVIO label to remove the REMS requirements is, I believe, a testament to the importance of TRYVIO. As shown in the Phase 3 PRECISION study, TRYVIO decreased systolic blood pressure by more than 15 mmHg from baseline in patients with confirmed resistant hypertensive despite treatment with a combination of antihypertensives. The durable efficacy was achieved with a good safety and tolerability profile. Decreasing BP to such an extent in these high cardiovascular risk patients is known to markedly decrease the risk of fatal and non-fatal cardiovascular events, such as strokes and myocardial infarctions. Idorsia will now work with a sense of urgency to make TRYVIO available in retail pharmacies and simplify the administration for prescribers, distributors, and ultimately for patients."

For the updated TRYVIO labeling, please see the Full Prescribing Information including BOXED Warning (PI and Medication Guide).

TRYVIO is commercially available through Walgreens Specialty Pharmacy. For more information visit the following websites:
US Healthcare Professionals: www.TRYVIOhcp.com
US Patients: www.TRYVIO.com

Notes to the editor

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 other antihypertensives in the European Union and the UK and marketing authorization applications are under review in Canada, and Switzerland.

About Idorsia
Idorsia Ltd is reaching out for more – we have more passion for science, we see more opportunities, and we want to help more patients.

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).

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