Media Release
March 17, 2025

Ad hoc announcement pursuant to Art. 53 LR

US FDA removes REMS requirement for TRYVIO (aprocitentan) – minimizing the burden on the healthcare delivery systems and patients

- FDA confirms that prescribers and pharmacists are no longer expected to interact with the REMS

Allschwil, Switzerland – March 17, 2025
Idorsia Ltd (SIX: IDIA) today announced that – effective immediately – the US FDA has fully released TRYVIO™ (aprocitentan) from its REMS (Risk Evaluation and Mitigation Strategy) requirement. 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 US FDA has determined that a REMS is 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. The FDA have therefore removed the requirement to minimize the burden on the healthcare delivery system of complying with the REMS.

Consequently, Idorsia is also released from the post marketing requirement (PMR) to conduct a worldwide descriptive study that collects prospective and retrospective data in women exposed to TRYVIO during pregnancy and/or lactation as these data are no longer needed. Idorsia no longer has post marketing requirements for TRYVIO.

Martine Clozel, Chief Scientific Officer of Idorsia, commented:
"As a dual endothelin receptor antagonist (ERA), TRYVIO targets a previously unaddressed but important pathway in systemic hypertension, the endothelin pathway. The FDA decision that a REMS is no longer necessary for TRYVIO reflects the progressive understanding of the risk / benefit of TRYVIO. The decision of the FDA is based on an evaluation of human fetal outcomes after exposure to a drug in the ERA class. This change is very important considering that TRYVIO can be prescribed to a large patient population, who have a high cardiovascular risk and whose hypertension could not be brought under control with the previous classes of medication. This comes on top of the outstanding properties of TRYVIO, the result of over 25 years of optimization in our drug discovery team."

Michael Moye, President and General Manager of Idorsia US, commented:
"TRYVIO is the first new antihypertensive working via a new pathway for over 40 years. It is a once-daily tablet, is easy to use for patients and easy to prescribe for physicians. In the absence of clinically relevant drug interactions, it can be safely combined with complex drug regimens and, importantly, can be used by chronic renal failure patients with hypertension without dose modification. On top of existing antihypertensives, aprocitentan has been shown to decrease systolic blood pressure by more than 15 mmHg from baseline at trough, and it is well tolerated over the long term. The release of the REMS is fantastic news as it makes TRYVIO even easier to prescribe. TRYVIO is available to prescribe today, and we are now looking for the best commercial solution to fully launch this important medication that fills a large unmet patient need."

Idorsia will submit revised labeling to the US FDA in accordance with the release of the REMS in the coming weeks.

For current information on TRYVIO see the Full Prescribing Information including BOXED Warning (PI and Medication Guide).

TRYVIO continues to be 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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