

Media Release

August 11, 2026

Ad hoc announcement pursuant to Art. 53 LR

Idorsia acknowledges the DEA proposal to reclassify dual orexin receptor antagonists to the lowest schedule – Schedule V

- The DEA states that dual orexin receptor antagonists “do not produce physical or psychological dependence”
- Lower schedule expected to enhance patient access in the US

Allschwil, Switzerland – August 11, 2026

Idorsia Ltd (SIX: IDIA) announces that the US Drug Enforcement Administration (DEA) will publish a proposed rule to reclassify dual orexin receptor antagonists (DORAs) from Schedule IV to Schedule V under the Controlled Substances Act (CSA). The proposal will be open to public comment for a duration of 30 days from publication – expected later today.

The DEA’s proposed rule follows a scientific and medical evaluation and scheduling recommendation from HHS, considering the statutory eight factors, which the DEA then reviewed in its own eight-factor analysis.

Jean-Paul Clozel, MD, Chairman and interim CEO of Idorsia, commented:

“We view the recommendation to reclassify to the least restrictive schedule V as an important first step. The proposed reclassification recognizes the favorable profile of daridorexant compared with traditional sedative-hypnotics. While we believe that the available evidence supports full descheduling, we will now analyze the proposal in detail and provide comments through the appropriate forum. We hope the continued removal of restrictions paves the way for more patients to benefit from the DORA class.”

Next steps

The DEA will accept public comments on the proposed rule before issuing a final decision.

About QUVIVIQ® (daridorexant) in the United States

QUVIVIQ is approved in the United States for the treatment of adult patients with chronic insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Notes to the editor

About Idorsia

The purpose of Idorsia is to discover, develop and commercialize innovative medicines to help more patients. To achieve this, we will develop 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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