



Media Release

October 27, 2026

Idorsia seeks US label update for QUVIVIQ daytime functioning benefits – first patients enrolled in Dari-Dream

Building on established clinical evidence, Dari-Dream is designed to further characterize the impact of QUVIVIQ on daytime functioning and support its inclusion in the US prescribing information.

Allschwil, Switzerland – October 27, 2026

Idorsia Ltd (SIX: IDIA) announced that the first patients are enrolled in Dari-Dream, a US label-enabling study evaluating QUVIVIQ® (daridorexant) 50 mg in adults and elderly people with insomnia disorder.

Insomnia disorder is a chronic, 24-hour condition that impacts not only sleep at night but also how people feel and function during the day. Beyond difficulties falling or staying asleep, people with insomnia experience symptoms that affect alertness, cognition, mood, energy, and daily functioning.

QUVIVIQ is supported by an extensive body of clinical evidence demonstrating not only benefits across nighttime symptoms of insomnia, but also daytime functioning. In the Phase 3 program, meaningful improvement with the 50 mg dose was observed across all three IDSIQ domains of alert/cognition, mood, and sleepiness as well as the overall IDSIQ score. These findings are reflected in prescribing information in multiple countries worldwide, including across Europe.

Following discussions with the US Food and Drug Administration, Dari-Dream has been specifically designed to further characterize these outcomes and support their inclusion in US prescribing information. Inclusion of daytime functioning information in the US label would support broader physician and patient education on an aspect of insomnia treatment that is highly relevant to people living with the disorder.

Amer Joseph, MD, Chief Medical Officer and Head of Global Clinical Development at Idorsia commented:

"Insomnia is a 24-hour condition that affects patients both during the night and throughout the following day. Daridorexant was specifically designed to provide efficacy across the night while minimizing next-morning residual sleepiness. Importantly, its differentiated profile as an equipotent dual orexin receptor antagonist may also contribute directly to improvements in daytime functioning. Building on the extensive evidence generated during the clinical development program, Dari-Dream is designed to further characterize these outcomes and support their inclusion in US prescribing information."

Roland Wandeler, Chief Executive Officer of Idorsia, commented:

"For people living with insomnia, the burden of the condition extends well beyond the night. Difficulties with alertness, mood, energy, and daily functioning can affect many aspects of everyday life. We have already generated compelling evidence demonstrating the benefits of daridorexant not only on sleep, but also daytime functioning. Dari-Dream is an important next step in our efforts to make this information available to healthcare professionals and patients in the US. Together with other initiatives aimed at enhancing the patient and physician experience, Dari-Dream forms part of our broader strategy to maximize the potential of QUVIVIQ for patients."

About Dari-Dream (NCT07843329)

Dari-Dream is a Phase 3, randomized, double-blind, placebo-controlled study evaluating QUVIVIQ (daridorexant) 50 mg in adults and elderly people with insomnia disorder. Approximately 344 participants will be randomized to receive daridorexant 50 mg or placebo once nightly for three months. The study will evaluate changes in subjective total sleep time as its primary endpoint. Key secondary endpoints include the Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ) sleepiness domain and total score, assessing the physical, emotional, and cognitive consequences of insomnia during the day. Results are expected during 2028.

Notes to the editor

QUVIVIQ – a different kind of insomnia treatment

Insomnia affects millions worldwide, yet commonly used treatments can lead to next-day drowsiness, dependence, and withdrawal symptoms – leaving a clear unmet need for safer, effective alternatives.

Discovered by Idorsia, QUVIVIQ works differently from traditional hypnotics. As a dual orexin receptor antagonist, it selectively targets the orexin system, helping to regulate overactive wake signaling without broadly suppressing brain activity. Its optimized pharmacokinetics promote restorative sleep throughout the entire night, reducing morning sleepiness, and improving daytime functioning.

Clinical trials published in The Lancet Neurology demonstrated that daridorexant significantly improved sleep onset, sleep maintenance, and self-reported total sleep time at 25mg and 50mg doses compared to placebo. Daridorexant 50 mg also demonstrated a highly significant improvement in daytime functioning compared to placebo, findings that are reflected in prescribing information in multiple countries worldwide.

Idorsia is building QUVIVIQ into a global brand

QUVIVIQ is marketed by Idorsia in North America and Europe, and is available in key international markets in Asia-Pacific and the Middle East through commercial partnerships. Idorsia also has a license and supply agreement for Latin America.

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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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