



# Media Release

## March 30, 2026

Ad hoc announcement pursuant to Art. 53 LR

### Idorsia's daridorexant delivers outstanding results in a Phase 2 study in children with insomnia disorder

- Phase 2 results show a statistically significant dose-dependent response on total sleep time with clinically meaningful improvements across multiple sleep measures in children with insomnia disorder, with especially pronounced efficacy in those with co-morbid neurodevelopmental disorders
- Excellent safety and tolerability of daridorexant confirmed for the first time in a pediatric population – including at the highest dose tested
- Idorsia to engage with health authorities to discuss next steps in pediatric insomnia and explore the potential of daridorexant for children with neurodevelopmental disorders
- Idorsia to host an investor webcast to discuss the study tomorrow, March 31, at 15:00hrs CEST

#### **Allschwil, Switzerland – March 30, 2026**

Idorsia Ltd (SIX: IDIA) announces positive top-line results from its Phase 2 dose-finding study evaluating 10, 25, and 50 mg doses of daridorexant – the company's dual orexin receptor antagonist (DORA) – in pediatric patients aged 10 to < 18 years with insomnia disorder.

Pediatric insomnia is characterized by difficulty initiating or maintaining sleep that is perceived as a problem by the child or caregiver due to its severity, chronicity, frequency, and the significant daytime impairment it causes for the child or the family.

The primary objective of the Phase 2 study ([NCT05423717](#)) was to characterize the dose-response relationship of daridorexant on objective total sleep time (TST), using polysomnography (PSG). Patients were randomized in a 1:1:1:1 ratio to 10, 25, or 50 mg daridorexant, or placebo for a treatment period of 2 weeks, with 165 patients receiving study medication. Analysis of the primary endpoint demonstrated a statistically significant ( $p=0.0185$ ) dose-dependent improvement in TST from baseline on Day 1, accompanied by additional dose-dependent improvements across multiple objective and subjective sleep parameters.

The study enrolled children with insomnia disorder aged 10-11 years (21%) and 12-17 years (79%), including those with a history of neurodevelopmental disorders, such as Autism Spectrum Disorder (ASD) and Attention-Deficit/Hyperactivity Disorder (ADHD).

Importantly, the study confirmed the excellent safety and tolerability profile of daridorexant for the first time in pediatric patients as young as ten. Even at 50 mg – the recommended adult dose – daridorexant's safety profile remained similar to placebo, with no adverse events denoting drug abuse during treatment and no indication of withdrawal symptoms upon treatment discontinuation.

Beyond sleep, the results suggest that orexin signaling may play a broader role in children with neurodevelopmental disorders, potentially opening an entirely new therapeutic avenue for these patients.

**Katharina Lederer, MD, Study physician and Master of Neuroscience at Advanced-Sleep-Research in Berlin, Germany, and principal investigator of the study, commented:**

"Pediatric insomnia is often chronic, and profoundly affects daytime functioning, mood, and cognitive and physical development. The impact is even greater in children with neurodevelopmental disorders where insomnia-driven daytime impairment may exacerbate the burden of the existing disorder. These Phase 2 findings are particularly exciting – treatment options for children and adolescents with insomnia remain extremely limited, and seeing robust efficacy without compromising safety constitutes a notable development in the field. Having been involved in the adult registration program for daridorexant, it is encouraging to see how similar the safety profile is in children, even at the highest dose."

**Professor Emerita Judith Owens, MD, MPH, Department of Neurology, Harvard Medical School, commented:**

"Pediatric insomnia is far more common than many realize – affecting 10-30% of children and adolescents in the United States, with even higher rates among those with neurodevelopmental disorders – and has a substantial negative impact on children's mood and emotional regulation, behavior, cognition and attention, and quality of life. While behavioral treatments for insomnia are successful in alleviating insomnia symptoms in many cases, there remains a critical need for safe and effective insomnia medications, especially in high-risk populations such as children with autism and ADHD. However, there are currently no FDA approved medications for pediatric insomnia. In addition, the safety concerns associated with the use of off-label drugs approved in adults to treat pediatric insomnia, has made clinicians understandably reluctant to use pharmacologic options, with a resultant gap in potential treatment options for the most affected children. The daridorexant Phase 2 results are compelling because they provide preliminary evidence of efficacy for pediatric insomnia alongside a reassuring safety profile."

**Alberto Gimona, MD, Head of Global Clinical Development & Medical Affairs of Idorsia, commented:**

"These positive results show for the first time that daridorexant delivers strong, dose-dependent improvements in both objective and subjective sleep outcomes in children. While the efficacy is compelling, the safety data are even more striking, including the visual analog scale where patients and caregivers estimate the feeling of the child's morning sleepiness – a safety measure of next-morning residual effect – showing no residual sleepiness but improved alertness. With a wealth of data to analyze, I'm looking forward to the discussions with health authorities to define the next steps in pediatric insomnia. As the only DORA being investigated in children, daridorexant could become not only best-in-class for adults, but first-in-class for the pediatric population."

**Martine Clozel, MD, Pediatrician, Chief Scientific Officer & Head of Research of Idorsia, commented:**

"The data are remarkable. We are not only helping young patients and their families – who urgently need evidence-based treatments when children suffer from chronic insomnia – but we are also seeing new signals that the orexin system may play an even more important role in neurodevelopmental disorders than previously understood. I cannot wait to present the data to the scientific community."

The study forms part of an FDA-approved Pediatric Study Plan and an EU PDCO-approved Paediatric Investigation Plan. Idorsia will now engage with health authorities to discuss next steps in pediatric insomnia and to initiate discussions on a new potential investigation pathway for children with neurodevelopmental disorders.

Detailed results will be shared at upcoming congresses and in peer-reviewed publications.



### Global availability

Daridorexant is marketed as QUVIVIQ for adult patients with insomnia by Idorsia in the US, Canada, and multiple European countries, and is available in Japan, Hong Kong, and China through commercial partnerships. Idorsia also has license and supply agreements with EMS in Latin America, CTS in Israel, and Pharmedica in the Gulf region.

**Daridorexant for pediatric use is investigational and not approved or marketed in any country.**

### Investor webcast

An investor webcast and conference call will be held to discuss the results on Tuesday, March 31, 2026, at **15:00 CEST / 14:00 BST / 09:00 EDT**.

### Live Webcast (audio + slides):

The live webcast can be accessed from the Idorsia website [www.idorsia.com](http://www.idorsia.com).

### Dial-in procedure for analysts (audio only):

Analysts who would like to ask questions are required to register in advance of the conference using the following link:

<https://register-conf.media-server.com/register/BI3a54a87a0d7640169345b16436338df7>

**Replay:** A replay of the investor webcast will be available through [www.idorsia.com](http://www.idorsia.com) approximately 60 minutes after the call has ended.

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## Notes to the editor

### About insomnia

Insomnia is defined as a combination of dissatisfaction with sleep and a significant negative impact on daytime functioning. Dissatisfaction with sleep refers to the difficulty to initiate and/or maintain sleep on at least three nights per week for at least three months, despite adequate opportunity to sleep.

Insomnia is a condition of overactive wake signaling and studies have shown that areas of the brain associated with wakefulness remain more active during sleep in patients with insomnia.

Insomnia as a disorder is quite different from a brief period of poor sleep, and it can take its toll on both physical and mental health. It is a persistent condition with a negative impact on daytime functioning. Idorsia's research has shown that poor-quality sleep can affect many aspects of daily life, including the ability to concentrate, mood, and energy levels.

The goals of managing insomnia are to improve sleep quality and quantity, as well as daytime functioning. Current recommended treatment of insomnia includes sleep hygiene recommendations, cognitive behavioral therapy and pharmacotherapy.

### About daridorexant – 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, daridorexant 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 in adult patients with insomnia at 25mg and 50mg doses compared to placebo. Daridorexant 50 mg also demonstrated a significant improvement in daytime functioning compared to placebo.

### About Dr Katharina Lederer

Katharina Lederer has been working as a study physician at Advanced-Sleep-Research GmbH (ASR) in Berlin since June 2016. ASR is a contract research organization (CRO) that specializes in the research and therapeutic influence of phenomena of the



sleep-wake rhythm. After studying medicine at the Charité in Berlin, Katharina Lederer completed her Master of Neuroscience at the University of Cape Town and worked in child psychiatry at the Königin-Elisabeth Herzberge Hospital in Berlin.

Katharina Lederer is a member of the Society for Sleep Research and Sleep Medicine (DGSM) and wrote her doctoral thesis on sleep, nutrition and the microbiome. She has been strengthening the team of the Schlafakademie Berlin since summer 2019. Dr Lederer served as a principal investigator in the pediatric study and acts as a consultant for Idorsia.

#### About Dr Judith Owens

Dr. Judith Owens is Professor Emerita of Neurology at Harvard Medical School and formerly a senior faculty member at the Pediatric Sleep Center at Boston Children's Hospital in Massachusetts. Recently retired from her clinical role, she remains an internationally recognized authority on pediatric sleep and continues to contribute her expertise to the field.

Dr. Owens has authored more than 175 original research and review articles, chapters, and books on pediatric sleep. Her research has focused on the neurobehavioral and health consequences of insufficient sleep in children and adolescents, including the impact of school start times, sleep health education, and the cultural and psychosocial factors that shape sleep behaviors. She has been involved in multiple pediatric clinical trials for children and adolescents with sleep disorders, including insomnia, obstructive sleep apnea and narcolepsy.

Dr. Owens is past president of the International Pediatric Sleep Association and received the World Sleep Society Distinguished Service Award in 2025. She received her undergraduate and medical degrees from Brown University and a master's degree in maternal and child health from the University of Minnesota. She completed fellowships in developmental behavioral pediatrics at Minneapolis Children's Medical Center and in child psychiatry at Brown University. Dr. Owens serves as a consultant for Idorsia.

#### 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).

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