



Media Release

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Idorsia presents outstanding results with daridorexant in children and adolescents with insomnia and an expanding body of evidence in adults at Sleep Europe 2026

Daridorexant, a dual orexin receptor antagonist, is the first investigational treatment in its class to demonstrate positive results in pediatric insomnia disorder, an area in which significant unmet needs remain for children and their families.

A single 50 mg dose increased sleep time by 50 minutes overall and 64 minutes in children with neurodevelopmental disorders, moving participants closer to their recommended age-appropriate sleep duration.

Daridorexant was well tolerated across doses including 50 mg, the highest recommended dose for adults, with a pediatric safety profile consistent with the established adult evidence

Sixteen presentations showcased the breadth of daridorexant research across adult clinical trials, real-world evidence and investigator-initiated studies in diverse populations with insomnia

Allschwil, Switzerland – October 23, 2026

Idorsia Ltd (SIX: IDIA) today announced results from the first and only Phase 2 study with a dual orexin receptor antagonist in children with insomnia disorder, presented to the scientific community at Sleep Europe 2026. Daridorexant featured prominently throughout the congress, with 16 Idorsia-sponsored and investigator-initiated presentations spanning pediatric and adult clinical research, real-world evidence, diverse populations with insomnia and changes in prescribing practice.

Professor Carmen M. Schröder, MD, PhD, Department of Child and Adolescent Psychiatry, Strasbourg University Hospitals, commented:

“This is the first controlled clinical study to show that a dual orexin receptor antagonist, with the right pharmacokinetic profile, can rapidly and meaningfully increase sleep duration in children and adolescents with insomnia disorder, without causing morning sleepiness. The clear dose-response and the consistency of the findings across objective and subjective sleep measures warrant further investigation in a Phase 3 study. While total sleep time improved in the overall children population, the results in children with neurodevelopmental disorders are particularly important, because insomnia worsens their core symptoms and comorbidities, while treatment options remain limited.”

Marked efficacy of daridorexant in children with insomnia

In pediatric age, insomnia disorder causes persistent night-time symptoms and significant daytime impairment for children and their families, yet treatment options remain limited, with no approved pharmacotherapies in the US.

The randomized, double-blind, placebo-controlled Phase 2 study ([NCT05423717](#), [Abstract](#)) evaluated treatment with daridorexant 10, 25 and 50 mg, or placebo, over two weeks in 165 children and adolescents aged 10 to under 18 years with DSM-5 insomnia disorder. More than half of the participants had a diagnosed or subthreshold neurodevelopmental disorder, including autism spectrum disorder and/or attention-deficit/hyperactivity disorder.

The study met its primary endpoint, demonstrating a **statistically significant dose-response in objectively measured total sleep time after the first dose.**

A single dose of daridorexant 50 mg increased objective total sleep time by 50 minutes from baseline, compared with 20 minutes with placebo (least-square mean). In children and adolescents with **neurodevelopmental disorders, daridorexant 50 mg increased objective total sleep time by 64 minutes from baseline**, compared with 27 minutes with placebo (least-square mean). After two weeks, in the overall population, caregiver-reported total sleep time increased from baseline by approximately 69 minutes with daridorexant 50 mg, compared with approximately 30 minutes with placebo (least-square mean).

Daridorexant 50 mg also provided the highest and most consistent improvements across measures of sleep initiation, sleep maintenance, and sleep quality while numerically reducing morning sleepiness.

Daridorexant was well tolerated across all doses studied. At 50 mg, the highest recommended adult dose, the **incidence of adverse events was similar to placebo, and the safety profile was consistent with the known adult safety profile.** No adverse events suggestive of abuse potential or physical dependence and no withdrawal symptoms were observed.

Professor Carmen M. Schröder concluded:

“The efficacy findings are compelling, and the favorable safety and tolerability results add to our confidence in taking the next steps. The highest recommended adult dose was studied in children, including those with lower body weight, with no new safety findings observed. This provides a strong foundation for the future development of daridorexant in pediatric populations”

Amer Joseph, MD, CMO and Head Global Clinical Development & Medical Affairs, commented:

“Once again, the properties that we designed into daridorexant – rapid absorption, rapid elimination, and a relatively short terminal half-life – have proven to provide efficacy through the night without negatively impacting the next morning. In fact, the safety measures show an improvement in next-morning alertness. The compelling results in children with insomnia and ADHD and/or ASD as well as in children without neurodevelopmental disorders allow us to target a broad and underserved pediatric population. As the only DORA being investigated in children, daridorexant could become not only the sole drug recommended by the ESRS guideline for short and long-term treatment of insomnia in adults, but also a first-in-class treatment for the pediatric population.”

Next steps in pediatric insomnia

The manuscript describing the full dataset is currently under evaluation with a high-ranked scientific journal. In parallel, the team is consolidating supportive comments from global health authorities on the protocol for the pediatric Phase 3 clinical development program. The company expects to initiate the new program in the second half of next year.

Presentation replay

A recording of Professor Carmen Schröder's presentation, featuring the same scientific content presented at Sleep Europe 2026, is available here: [Watch the presentation](#)

An expanding evidence base in adults

Beyond the pioneering pediatric study, **15 additional presentations demonstrated the growing breadth of evidence for daridorexant in adults.** Across controlled clinical studies and routine clinical practice, improvements were observed in objective and subjective sleep measures, insomnia severity

and daytime functioning, including in adults with psychiatric, neurological and neurodevelopmental comorbidities.

In adults with insomnia and objectively measured short sleep duration, three months of continuous daridorexant 50 mg treatment improved sleep onset, sleep maintenance and total sleep time, based on both objective and subjective measures.

Investigator-initiated research further reported **improvement of sleep with daridorexant in menopausal women with insomnia and in patients with insomnia and epilepsy, major depressive disorder or sedative-hypnotic use disorder.**

The **growing real-world evidence also showed improvements beyond the night.** Prospective and retrospective studies reported reductions in insomnia severity alongside improvements in depressive symptoms, **quality of life, and work productivity.**

Finally, a separate analysis of prescribing patterns across six countries found that increased DORA use coincided with **reductions in benzodiazepine and Z-drug use, two classes of drugs associated with public safety concern.** The overall volume of insomnia medication was not changed.

Dieter Kunz, M.D., Director of the Sleep Research and Clinical Chronobiology Research Group at Charité - Universitätsmedizin Berlin, commented:

“The research presented at Sleep Europe demonstrates both the breadth and maturity of the evidence for daridorexant. Across controlled studies and routine clinical practice, improvements were observed in objective and subjective sleep, insomnia severity and daytime functioning, including in patients with complex psychiatric, neurological and neurodevelopmental comorbidities. These findings show that the benefits established in the pivotal program are increasingly being observed in the diverse patients we treat in everyday practice. At the same time, prescribing data suggest that when DORAs are accessible, clinical practice can move away from traditional hypnotics, which are symptomatic only, towards a more disease-modifying-type of treatment for insomnia disorder.”

An exploratory study in adults with ADHD and insomnia reported improvements in insomnia symptoms and sleep parameters in nearly two-thirds of patients after four weeks of daridorexant treatment, alongside improvements in measures of attention, mood, and anxiety.

Giacomo Grassi, M.D., Ph.D., psychiatrist and researcher at Brain Center Firenze, commented:

“A growing number of real-world studies show that the efficacy of daridorexant observed in clinical trials is also seen in the complex clinical populations we treat every day. This is particularly relevant for adults with ADHD, in whom sleep problems are the rule rather than the exception, and for whom, until now, we had no evidence-based options for treating insomnia. The good news is that our real-world data suggest that daridorexant may represent a valuable treatment option for a substantial proportion of patients with ADHD and insomnia disorder. Sleep should be routinely assessed in these patients, and insomnia should be treated according to the guidelines.”

Global availability

Daridorexant is marketed as QUVIVIQ for adult patients with insomnia by Idorsia in North America and Europe and is available in key Asia-Pacific and Middle East markets through commercial partnerships.

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

Notes to the editor

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 pediatric insomnia

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.

About the pediatric Phase 2 study ([NCT05423717](#))

The multicenter, randomized, double-blind, placebo-controlled Phase 2 dose-finding study evaluated daridorexant 10, 25 and 50 mg, or placebo, over two weeks in 165 children and adolescents aged 10 to under 18 years with insomnia disorder. The primary objective of the Phase 2 study 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. The primary endpoint was the change from baseline to Day 1 in TST measured by PSG. Additional assessments included objective and subjective sleep measures, sleep quality, morning sleepiness and alertness, daytime functioning, pharmacokinetics, safety and tolerability.

The study included children and adolescents with insomnia disorder without neurodevelopmental disorders, participants with subthreshold autism spectrum disorder or attention-deficit/hyperactivity disorder traits, and participants with diagnosed neurodevelopmental disorders.

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.

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.

About Professor Schröder

Carmen Schröder, MD, PhD, is Professor of Child and Adolescent Psychiatry at Strasbourg University and head of the Department of Child and Adolescent Psychiatry at Strasbourg University Hospitals in France, as well as the coordinator of the Excellence Centre for Autism and Neurodevelopmental disorders STRAS&ND and the Centre for Rare Diseases with genetic expression. Prof. Schröder's career trajectory is international: of German origin, she has studied medicine in Germany and France, before specializing first in General Psychiatry and then in Child and Adolescent Psychiatry in France, Switzerland (Basel) and the United States (post-doctorate and junior faculty, Stanford University). She represents France since 2016 within the European Union of Medical Specialists for CAP (UEMS-CAP) and has served as its president between 2020 and 2026; she is also on the Board of Directors of the European and of the International Association of CAP (ESCAP, since 2023).

Beyond her CAP positions, Prof. Schröder is a European ESRS Board-Certified Sleep expert and is the national coordinator of the French sleep diploma. Her main clinical and research interests (within a CNRS group at the Institute for Cellular and Integrative Neurosciences in Strasbourg) are focused on sleep and circadian rhythm disturbances in children and adolescents, in particular in neurodevelopmental disorders such as autism and ADHD. She has published more than 100 publications, mostly on implications of sleep disorders and/or circadian rhythm disorders on child's development or child and adolescent psychiatric disorders. Prof Schröder serves as a consultant for Idorsia.

About Dr Kunz

Dieter Kunz, M.D., is Head of the Clinic of Sleep & Chronomedicine at St. Hedwig Hospital in Berlin, Germany, and Director of the Sleep Research and Clinical Chronobiology Research Group at Charité - Universitätsmedizin Berlin. A board-certified psychiatrist and somnologist, he has dedicated much of his career to the diagnosis and treatment of sleep disorders and to advancing research in sleep medicine and chronobiology. Dr. Kunz has served as principal investigator in numerous clinical studies and is widely recognized for his contributions to the understanding of sleep regulation and circadian biology.

About Dr Grassi

Giacomo Grassi, MD, PhD, is a Surgeon, specialized in Psychiatry and has a PhD in Neuroscience cum laude from the University of Florence. His clinical activity focuses on the pharmacological and non-pharmacological treatment of neuropsychiatric disorders. He deals with mood and anxiety disorders and is an expert in impulsive-compulsive spectrum disorders and attention deficit hyperactivity disorder (ADHD). He is an expert in neuromodulation therapy (transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS)) applied to treatment-resistant neuropsychiatric disorders (mood disorders, anxiety disorders, obsessive-compulsive spectrum disorders, attention deficit hyperactivity disorder, behavioral addictions). In these areas she carried out research at the Academic Medical Center of Amsterdam between 2013 and 2014 and carried out clinical and research activities at the Institute of Neuroscience in Florence from 2015 to 2019.

Dr Grassi carries out research in the field of ADHD, obsessive-compulsive disorder and neuromodulation and is the author of numerous scientific publications in international journals (see CV). Since 2017 he has been elected a member of the board of directors of the International College of Obsessive-Compulsive Spectrum Disorders (ICOCs, UK) of which he is still a member and in 2018 he was appointed a member of the board of directors of the Italian Academy of Behavioral Addiction Sciences (AiSdICO). He is also a member of the ADHD World Federation. For neuromodulation he is a member of the European Society for Brain Stimulation (ESBS) and the Clinical TMS Society.

He is a member of the editorial board of the international journal Comprehensive Psychiatry and the Brazilian Journal of Psychiatry and works as a peer-reviewer of many international journals of psychiatry and neuroscience. Dr Grassi serves as a consultant for Idorsia.

About Sleep Europe 2026

Sleep Europe 2026, the 28th Congress of the European Sleep Research Society, will take place in Maastricht, the Netherlands, from October 20 to 23, 2026. Held every two years, the congress brings together more than 3000 clinicians, researchers, scientists and other sleep professionals to share and discuss the latest advances in sleep medicine and sleep research.

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).

For further information, please contact:

Investor & Media Relations

Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil

+41 58 844 10 10

investor.relations@idorsia.com – media.relations@idorsia.com – www.idorsia.com

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