



Media Release

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Ad hoc announcement pursuant to Art. 53 LR

A new scientific avenue for daridorexant: Idorsia to advance development in autism spectrum disorder

In a Phase 2 study in pediatric insomnia disorder, in addition to marked improvements in sleep measures, daridorexant 50 mg showed an unexpected pattern of improvement in affect and behavior, cognition, and daily activities in participants with autism spectrum disorder (ASD) or subthreshold ASD characteristics.

Idorsia in-house research data and published scientific research, as well as the unique profile of daridorexant, further support the rationale for its investigation in the treatment of ASD.

Idorsia will therefore pursue a new development program for daridorexant in ASD, with program details expected in the first half of 2027 following discussions with health authorities.

Allschwil, Switzerland – October 26, 2026

Idorsia Ltd (SIX: IDIA) today announced that it is advancing a new development program to investigate daridorexant in autism spectrum disorder (ASD). The company is working on a dedicated formulation in parallel to discussions with global health authorities about the development program design in ASD, including the doses to be investigated. Further details will be shared in H1 2027.

Roland Wandeler, Chief Executive Officer, commented:

“We are intrigued by the observation from our clinical research that has opened an entirely new scientific avenue for daridorexant and Idorsia. The opportunity to investigate a potential new treatment approach for a condition where treatment options remain extremely limited gives this program particular significance. In addition to its potential impact for people living with ASD and their families, this opportunity demonstrates the value of combining rigorous analysis of our data with deep scientific understanding to uncover important new opportunities for patients and create long-term value for the company.”

The decision is based on findings from Idorsia’s randomized, placebo-controlled Phase 2 study of daridorexant in 165 children and adolescents with insomnia disorder, recently presented at Sleep Europe 2026 ([Press release](#)). The study evaluated objectively measured total sleep time after one dose of daridorexant 10, 25, and 50 mg. More than half of participants had diagnosed or subthreshold neurodevelopmental disorder, including ASD or attention-deficit/hyperactivity disorder (ADHD).

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder characterized by persistent impairments in social communication and interaction and by restricted or repetitive behaviors, interests, or activities. Support needs vary widely, with some people requiring lifelong care. ASD affects an estimated 61.8 million people worldwide. In the United States alone, it affects around 1 in 31 eight-year-old children.

Professor Carmen Schröder MD, PhD, Department of Child and Adolescent Psychiatry, Strasbourg University Hospitals, and member of Idorsia's Autism Advisory Board commented:

"Every child with autism spectrum disorder is different, but for many, difficulties with communication, social interaction, and everyday functioning can shape almost every part of childhood and continue throughout life. Families often carry that burden alongside them, providing extraordinary levels of practical and emotional support while searching for therapeutical interventions that remain extremely limited. With no approved pharmacological treatment addressing the core features of ASD, investigating a new treatment approach offers much-needed hope for children, their caregivers and families, and the clinicians who care for them."

Daridorexant had a distinct positive impact on affect and behavior, cognition, and daily activities for children with ASD.

At the Society for Developmental and Behavioral Pediatrics Annual Meeting, Idorsia presented an analysis of data from the participants with ASD or subthreshold ASD randomized in its dose-relationship study of daridorexant in children with insomnia disorder.

A single dose of daridorexant 50 mg, the highest recommended dose in adults, consistently improved the sleep parameters, including objective total sleep time in participants with ASD, ADHD, or no neurodevelopmental disorder.

The PROMIS Pediatric Sleep-Related Impairment questionnaire was used to assess the impact of sleep-related problems on daytime functioning. After only two weeks of treatment with daridorexant 50 mg, participants with ASD showed a distinct, consistent, and differentiated exploratory pattern of improvement across multiple facets of functioning compared to the overall population. The magnitude of impact was particularly noticeable on affect and behavior, cognition, and daily activities, facets highly relevant in ASD.

The consistent effect on sleep parameters across all participant subpopulations contrasting with the distinct exploratory pattern in participants with ASD on functioning may suggest that the observed effect is not solely mediated by an improvement in sleep but could extend to a treatment effect on autism spectrum disorder itself.

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

"The initial findings on improved sleep were already exciting for clinicians caring for children with insomnia, a highly underserved population. To then see a signal emerge early on in children with ASD, beyond insomnia, is even more powerful. The findings suggest that daridorexant could open a new avenue for patients with ASD. These findings now deserve prospective evaluation in a dedicated clinical program to determine whether the signal can be confirmed and translated into a meaningful benefit for children with ASD and their families."

A solid scientific rationale for the role of the orexin system in ASD

Following the unexpected clinical findings, further investigation revealed a biological rationale for orexin receptor antagonism in ASD.

Firstly, daridorexant, the investigated drug, is a dual orexin receptor antagonist that equipotently blocks orexin signaling through both the OX1 and OX2 receptors. Both receptors may be implicated in several functions including social interaction, behavioral flexibility, attention, motivation, stress response, and emotional regulation, several of which are affected in autism spectrum disorder.

Internal data analysis suggests a gene expression signature in autistic brain tissue that may indicate increased orexin signaling. Published findings reporting altered orexin levels in children with ASD provide additional external support for investigating the pathway.⁵

Martine Clozel, MD, Chief Scientific Officer and Head of Research, commented:

“The distinct response observed in children and adolescents with ASD was unexpected. Together with our in-house findings suggesting high orexin signature in autism, and a growing understanding of how the OX1 and OX2 pathways may influence functions commonly affected in ASD, these observations provide a compelling scientific hypothesis for prospective evaluation. As an equipotent dual orexin receptor antagonist, daridorexant is particularly well suited. As a pediatrician, I personally find this new avenue of research both compelling and exciting.”

Notes to the editor

About daridorexant

The pharmacokinetic characteristics of daridorexant, Idorsia’s dual orexin receptor antagonist, including rapid absorption, rapid elimination, and a relatively short terminal half-life, provide activity throughout the night while limiting next-morning drug exposure and avoiding accumulation with repeated dosing.

About autism spectrum disorder⁹⁻¹¹

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder characterized by persistent impairments in social communication and interaction and by restricted or repetitive behaviors, interests, or activities. Support needs vary widely, with some people requiring lifelong care. ASD affects an estimated 61.8 million people worldwide, approximately 1 in 127. In the United States, it affects around 1 in 31 eight-year-old children, is more than three times as prevalent among boys as girls, and affects an estimated 5.4 million adults.

The disorder can profoundly affect relationships, education, employment, independence, and community participation. Nearly 40% of young people with ASD spend little or no time with friends, and most continue to live with relatives into adulthood, often requiring substantial practical, emotional, and financial support from families and caregivers.

Treatment options are very limited and primarily address associated symptoms or co-occurring conditions. No pharmacological treatment is approved for the core features of ASD, underscoring the need for new biological approaches.

Diagnostic criteria of ASD and related functions of the orexin system

Mood, motivation, reward processing, cognition, and social interaction are important facets of ASD. The orexin system could play a role in these functions as summarized in the table below.^{1,4,5}

Diagnostic criteria of ASD and potential role of the orexin system

DSM-5 Criteria for ASD*	Potential role of orexin in ASD or other populations
Impairment in social interactions and communication	Orexin might modulate social motivation, social reward processing , salience attribution, and social approach behavior. Altered orexin signaling could reduce engagement with social stimuli and social interactions ⁴
Restricted and repetitive behavior, interests and activities	Orexin may be involved in reward-seeking, habit formation, compulsive behaviors , perseveration, and motivational drive . Dysregulated orexin signaling could theoretically contribute to repetitive or restricted behavioral patterns ^{4,6}
Limited and hindered everyday activities	Orexin is a major regulator of wakefulness, alertness, attention, executive functioning, motivation, and cognitive performance , all of which influence daily functioning and possible adaptive behavior ^{4,7}

* the other criterion is: symptoms must be present in the early developmental period.¹

About Professor Carmen Schröder, MD

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 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.

References

1. Forrest CB, et al. Development and validation of the PROMIS Pediatric Sleep Disturbance and Sleep-Related Impairment item banks. *Sleep*. 2018;41(6):10.1093/sleep/zsy054. doi:10.1093/sleep/zsy054
2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013. doi: 10.1176/appi.books.9780890425596
3. Graham Holmes L, et al. A Lifespan Approach to Patient-Reported Outcomes and Quality of Life for People on the Autism Spectrum. *Autism Res*. 2020;13(6):970-987. doi:10.1002/aur.2275
4. Ouaidat S, et al. Orexins/Hypocretins: Gatekeepers of Social Interaction and Motivation. *Int J Mol Sci*. 2024;25(5):2609. Published 2024 Feb 23. doi:10.3390/ijms25052609
5. Sayer S, et al. Assessment of the Role of Orexin A and Some Clinical Parameters in Children with Autism Spectrum Disorder. *Med Health Sci*. 2025;3(1). doi: 10.21070/anamnetic.v3i1.1611
6. Merlo Pich E, et al. Orexin 1 receptor antagonists in compulsive behavior and anxiety: possible therapeutic use. *Front. Neurosci*. 2014;8:26. doi: 10.3389/fnins.2014.00026
7. Mignot E, et al. Safety and efficacy of daridorexant in patients with insomnia disorder: results from two multicentre, randomised, double-blind, placebo-controlled, phase 3 trials. *Lancet Neurol*. 2022;21(2):125-139. doi:10.1016/S1474-4422(21)00436-1
8. Schröder C, et al. The dual orexin receptor antagonist daridorexant in pediatric insomnia disorder The dual orexin receptor antagonist daridorexant in pediatric insomnia disorder. Abstract presented at Sleep Europe 2026, October 23, Maastricht. Available [here](#). Last accessed 23.10.2026
9. CDC. Data and Statistics on Autism Spectrum Disorder. Available [here](#). Last accessed October 2026.
10. Global Burden of Disease Study 2021 Autism Spectrum Collaborators. The global epidemiology and health burden of the autism spectrum: findings from the Global Burden of Disease Study 2021. *Lancet Psychiatry*. 2025;12(2):111-121. doi:10.1016/S2215-0366(24)00363-8
11. Hodis B, et al. Autism Spectrum Disorder. [Updated 2025 Jan 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/sites/books/NBK525976/>

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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