



Media Release

March 14, 2025

Idorsia announces the publication of positive data with daridorexant in patients with chronic insomnia and nocturia

- Daridorexant, Idorsia's dual orexin receptor antagonist, shows consistent efficacy across both insomnia- and nocturia-related endpoints in a placebo-controlled study in patients with chronic insomnia and nocturia
- In this study, daridorexant was safe and well tolerated, consistent with the well-documented safety profile observed in the Phase 3 studies in chronic insomnia.
- The data from the Phase 4 study is published in the *Journal of Sleep Research*
- On World Sleep Day, Idorsia unites with the World Sleep Society in the call to make sleep health a priority

Allschwil, Switzerland – March 14, 2025

Idorsia Ltd (SIX: IDIA) today announced the publication of "[A randomized cross-over trial of daridorexant for the treatment of chronic insomnia and nocturia](#)" in the *Journal of Sleep Research*.

The new data provides evidence of the benefit of Idorsia's dual orexin receptor antagonist, daridorexant (QUVIVIQ™), at a daily dose of 50 mg, in patients aged ≥ 55 years with chronic insomnia and comorbid nocturia, with efficacy data on symptoms of both conditions, improvement in daytime functioning, and a good safety and tolerability profile.¹

Chronic insomnia is defined as difficulty initiating and/or maintaining sleep at least three times a week for a minimum of three months and a significant negative impact on daytime functioning. Nocturia is waking during the night due to the need to urinate. Insomnia and nocturia frequently co-exist, particularly in older patients, and each may contribute to poor sleep quality, impaired daytime functioning and low quality of life.

Katharina Lederer, MD, Advanced-Sleep-Research GmbH (ASR) in Berlin, Germany, and the coordinating investigator in the study, commented:

"In patients needing to frequently visit the bathroom during the night, insomnia is very common and a significant burden for patients. The results that have been generated in this study are remarkable. Not only have we seen consistent efficacy after a short treatment period and across the insomnia measures – including increasing total sleep time and an impressive effect on insomnia severity – but also there was a great effect on their nocturia. What's more, patients also experienced improved next-day functioning and consequently reported significantly higher satisfaction after treatment with daridorexant versus placebo. I hope that the ability to affect both comorbidities will encourage a more joined-up thinking for specialists of both conditions to adequately treat these patients."

José Emilio Batista, MD, Director of the Urology Department in Teknon Medical Center, Spain, and an investigator in the study, commented:

"Many people visit the toilet during the night, go straight back to sleep and think nothing more of it. For these people, it is difficult to understand the impact that nocturia can have. The patients enrolled in this study are waking 3, 4 and sometimes 5 or more times during the night to use the toilet, so quite severe nocturia symptoms. When combined with insomnia, the patients are badly affected by the disruption, with many not able to function well the next day. The results in the study show that the patients are able to sleep longer before the first visit to the toilet and need to go fewer times, these are certainly clinically meaningful results."

About the Phase 4 study in comorbid insomnia and nocturia¹

In total, 60 patients – equally split between male and female patients – aged 55 or older with insomnia and comorbid nocturia participated in this multi-national, multi-center, double-blind, randomized, placebo-controlled, 2-way cross-over study. The study consisted of 2 treatment periods of 4 weeks each, separated by a 2-3-week washout period.

In the study, daridorexant 50 mg significantly improved subjective total sleep time (sTST) from baseline to Week 4 of treatment (primary endpoint) and other measures of sleep and daytime functioning. Insomnia Severity Index (ISI) score was reduced, with one and a half as many patients treated with daridorexant vs placebo improving by ≥ 6 units, the threshold of clinical relevance. The impact of insomnia on patients' daytime functioning was measured daily using the Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ). Improvements in sTST, quality and depth of sleep, and daytime functioning were seen as early as Week 1 of treatment and were maintained throughout the treatment period.¹

Treatment with daridorexant 50 mg also reduced the number of nocturnal voids (nighttime visits to the toilet) from baseline to Week 4 and improved other nocturia-related symptoms, such as an increase in time to first void. A short time to first void is associated with increased daytime dysfunction and decreased sleep quality, quantity and/or sleep efficiency.¹

Daridorexant 50 mg in patients with chronic insomnia and comorbid nocturia was safe and well tolerated¹, consistent with the well-documented safety profile observed in the Phase 3 studies in chronic insomnia². No serious AEs/AEs leading to discontinuation were reported in the study. Importantly, in terms of adverse events of special interest, there were no urinary incontinences, and no falls observed in patients treated with daridorexant.¹

Antonio Olivieri, MD, Chief Medical Officer & Head of Global Medical Affairs, commented:

“We already have incredibly strong and robust data demonstrating that daridorexant is an effective treatment of insomnia disorder with an optimal duration of action and a well-documented safety profile. Nonetheless, I am very impressed with the study results because here we see that daridorexant has a positive effect on both insomnia and nocturia endpoints. After a short treatment period, patients reported a significant improvement on the quality of their nights' sleep and importantly, also on their days. I am very proud that Idorsia is leading the way in building evidence on the burden of insomnia and furthering the science of sleep.”

World Sleep Day

Today marks World Sleep Day, a significant annual awareness event within the global sleep community. Sleep is one of the three key pillars of health, alongside healthy diet and exercise, and lays the foundation to our physical, mental, and social well-being.

Sleep disorders such as insomnia can lead to a lack of quality, restorative sleep. When people experience problems falling or staying asleep for at least three days a week, for at least three months with significant impact on their daytime activities, their insomnia is defined as chronic. Despite 6-10% of adults living with chronic insomnia, the condition is often not recognized, and the negative impact underestimated.

Benjamin Limal, President of Europe and Canada region, commented: “All of us at Idorsia are proud supporters of World Sleep Day, and we are united with the World Sleep Society in the call to action to make sleep health a priority. We support patients, advocates and the medical community in elevating the conversation around sleep and emphasizing the significant, and often hidden, impact chronic sleep disorders have on individuals and society.”

To access information and resources for people living with chronic insomnia, including a guide to help discuss symptoms with a doctor, visit [World Sleep Day 2025](#).

Notes to the editor

About daridorexant

Daridorexant is Idorsia's dual orexin receptor antagonist (DORA) which blocks the binding of the wake-promoting orexin neuropeptides. Rather than inducing sleep through broad inhibition of brain activity, daridorexant only blocks the activation of orexin receptors and reduces the overactive wake drive shown in individuals with chronic insomnia. Daridorexant is commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, France, Sweden, and Japan, and is approved throughout the EU, and in Hong Kong.

About the Phase 4 study in comorbid insomnia and nocturia¹

In total, 60 patients – equally split between male and female patients – aged 55 or older with insomnia and comorbid nocturia participated in this multi-national, multi-center, double-blind, randomized, placebo-controlled, 2-way cross-over study. The study consisted of 2 treatment periods of 4 weeks each, separated by a 2-3-week washout period.

The primary objective of the study was to assess the efficacy of daridorexant 50 mg daily on insomnia by measuring subjective total sleep time (sTST) by the Sleep Diary Questionnaire (SDQ). Other sleep-related endpoints included the overall rating of the insomnia severity by the Insomnia Severity Index® (ISI®), and SDQ-derived variables like quality of sleep visual analog scale (VAS), depth of sleep VAS, daytime alertness VAS, daily ability to function VAS, and number of awakenings.

The secondary objective was to assess the efficacy of daridorexant on nocturia by evaluating the number of nocturnal voids, the time to the first nocturnal void, each voiding volume (nighttime and daytime) including total volume, lower urinary tract symptoms (LUTS) sub-score using the International Consultation on Incontinence Questionnaire (ICIQ) -MLUTS and -FLUTS for male and female subjects, and quality of life relative to nocturia, assessed by ICIQ Nocturia Quality of Life (ICIQ-NQoL).

Other endpoints included a change in daytime functioning (Insomnia Daytime Symptoms and Impacts Questionnaire score, IDSIQ). Other objectives focused on patient's overall assessment ratings of their condition and symptoms, as well as patients' safety using various questionnaires.

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.³

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 is a common problem with a prevalence of approximately 10% worldwide. On this basis, and assuming a US adult population of around 250 million, there are approximately 25 million adults in the US who suffer from 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 nocturia

Nocturia is waking during the night due to the need to urinate and is considered clinically relevant if someone needs to urinate at least twice each night. It is one of the main causes of sleep disruption, including frequent awakenings with patients having difficulties returning to sleep.⁴ Already two or more voids per night have been associated with significant burden for the patients and were linked to next day impairments.

Nocturia is a predictor for insomnia, with an increased number of voids per night associated with worsened sleep quality and quality of life.^{5,6,7} Insomnia is common in patients suffering from frequent night-time voiding and should be adequately treated. There is a high unmet medical need to identify effective and safe treatments targeting the frequent sleep complaints in this patient population.

References

1. Lederer K et al. *Journal of Sleep Research*. 2025. doi: 10.1111/jsr.70002
2. Mignot E et al. *Lancet Neurol*. 2022;21(2):125-139.
3. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed., Text Revision. *American Psychiatric Publishing*. 2022.
4. Ancoli-Israel S, Bliwise DL, Nørgaard JP. The effect of nocturia on sleep. *Sleep Med Rev*. 2011;15(2):91-97. doi:10.1016/j.smrv.2010.03.002
5. Asplund R, Aberg H. Health of the elderly with regard to sleep and nocturnal micturition. *Scand J Prim Health Care*. 1992 Jun; 10(2):98-104.
6. Bliwise DL, Foley DJ, Vitiello MV, Ansari FP, Ancoli-Israel S, Walsh JK. Nocturia and disturbed sleep in the elderly. *Sleep Med*. 2009 May; 10(5):540-8.
7. Yu HJ, Chen FY, Huang PC, Chen TH, Chie WC, Liu CY. Impact of nocturia on symptom-specific quality of life among community-dwelling adults aged 40 years and older. *Urology*. 2006 Apr; 67(4):713-8

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Dr José Emilio Batista serves as a consultant to Idorsia and was an investigator in the study.

About Idorsia

Idorsia Ltd is reaching out for more – we have more passion for science, we see more opportunities, and we want to help more patients.

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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