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Idorsia shares new analyses of daridorexant for patients with insomnia at World Sleep 2025

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Idorsia Ltd (SIX: IDIA) shares new analyses of daridorexant for patients with insomnia and further characterizes insomnia disorder at World Sleep 2025, delivering on its ongoing commitment to further the science of sleep and insomnia.

Antonio Olivieri, MD, Chief Medical Officer & Head of Global Medical Affairs, commented: "The World Sleep Society has once again delivered an outstanding event that advances the science of sleep and insomnia. I am especially encouraged to see the growing recognition of the role of the orexin system in insomnia disorder and the impact effective treatment can have for patients. The real-world data presented with daridorexant in patients with neurological and psychiatric comorbidities are particularly compelling. I thank the organizers and participants for their valuable contributions."

Real-world data assessment of abuse potential of insomnia therapies

 Real-world data on the abuse potential of medications for the treatment of insomnia. P. Saskin, W.V. McCall, D. Neubauer, A. Crucitti, P.P. Luyet, R. Jaziri, C. Vaillant. <u>Abstract available online</u> | <u>View the poster</u> | <u>Read dedicated press release</u>

Analysis of the FAERS database, designed to interpret the real-world abuse potential of medications used for the treatment of insomnia disorder, suggests that the real-world abuse potential of the DORA class is very low and markedly lower than those seen for other scheduled and non-scheduled insomnia therapies.

Efficacy of daridorexant throughout the night

- Effect of daridorexant on wakefulness throughout the night: Post-hoc analysis of a randomised, double-blind, active reference (zolpidem) study in patients with insomnia disorder. B. Steiniger-Brach, O. Briasoulis, A. Olivieri, S. Pain, L. Palagini, D. Kunz, P.-A. Geoffroy. Abstract available online | View the poster
- Effect of daridorexant on wakefulness throughout the night and morning sleepiness in patients with insomnia disorder. Y. Dauvilliers, G. Zammit, P.-P. Luyet, G. Braunstein, O. Briasoulis, A. Olivieri. Abstract available online | View the poster

A post-hoc analysis of a randomized, double-blind study, where individuals with insomnia disorder received either daridorexant, zolpidem or placebo. Daridorexant reduces wakefulness after sleep onset (WASO) in a dose-dependent manner across all quarters of the night. Daridorexant 50 mg not only alleviated early awakening, but also showed numerically greater reductions in WASO during the second half of the night compared with zolpidem 10 mg. These results reinforce daridorexant's ability to reduce wakefulness along the entire night, including the second half where commonly used hypnotics fail to differentiate from placebo. In addition, in the post-hoc analysis of a Phase 3 trial, daridorexant showed similar findings, reducing WASO consistently across all quarters of the night, including the final two hours when sleep maintenance is most challenging. Moreover, treatment was also associated with improving morning sleepiness, daytime alertness, and ability to function, with stronger and more consistent effects observed at 50 mg. These findings highlight daridorexant's



clinical value in maintaining sleep throughout the night without causing next-morning or daytime sleepiness.

Impact of daridorexant in patients with insomnia and additional health conditions

• Efficacy and safety of daridorexant in women with insomnia disorder during menopausal transition: a subgroup analysis. O. Briasoulis, Z. Schaedel, C. Bassetti, S.M. Bertisch, P. Cassel, S. Palacios, C. Palmay, R. Silvestri, P. Stute, F. Trémollieres, T. Bakker, S. Pain. Abstract available online | View the poster

In the first subgroup analysis to evaluate daridorexant in women with insomnia disorder during the menopausal transition, daridorexant 50 mg improved sleep onset, sleep maintenance, and daytime functioning, with no increased risk of next-morning sleepiness or daytime safety concerns. These results highlight daridorexant as a well-tolerated and effective treatment option for this underserved population.

• Efficacy and safety of daridorexant in patients with chronic insomnia disorder and comorbid nocturia. K. Lederer, S. Schoffner, J.-E. Batista Miranda, R. Rowles, A. Olivieri, M. Meinel.

<u>Abstract available online</u> | <u>View the poster</u>

Data from patients with chronic insomnia and comorbid nocturia showed that daridorexant 50 mg improved sleep duration and insomnia severity, with associated benefits in daytime functioning. Treatment also reduced nocturia symptoms without causing falls, urinary incontinence, or next-day residual effects. These results support daridorexant as a well-tolerated and effective option in this challenging population.

Characterization of patients with insomnia disorder

- The impact of insomnia disorder on the night and the day: analysis of polysomnography and subjective parameters from a large clinical trial database. M. Fernandes, A. Olivieri, O. Briasoulis, J. Laurent, C. Liguori. Abstract available online | View the poster
- The impact of insomnia disorder on the night and the day in older and younger adults. M. Fernandes, A. Olivieri, O. Briasoulis, J. Laurent, C. Liguori. Abstract available online | View the poster
- The impact of insomnia disorder on the night and the day in males and females. M. Fernandes, A. Olivieri, O. Briasoulis, J. Laurent, C. Liguori. Abstract available online | View the poster

While effective management of insomnia disorders requires addressing both nighttime and daytime symptoms, studies assessing both the nocturnal and diurnal clinical features have been limited. Using data from more than 5000 patients screened in the Phase 3 daridorexant program, a series of three posters provided important insights into the wide-ranging impact of insomnia disorder in a broad patient population. Subgroup analyses demonstrated that insomnia disorder negatively impacts sleep and daytime functioning across sexes and age groups. Together, these findings reinforce the importance of developing and delivering treatments that address the full multidimensional burden of insomnia disorder, by improving both nighttime sleep and daytime functioning.

About World Sleep 2025

World Sleep 2025 was the 18th World Sleep Congress. The congress facilitated an international discussion forum and collaboration among sleep societies and sleep professionals. Sleep clinicians, technologists, trainees, educators, and scientists from around the world met to advance knowledge on sleep science, sleep in public health, sleep health and the sleep-wake disorders, their diagnosis and treatments.



Notes to the editor

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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