



Media Release

June 9, 2021

Idorsia to present new Phase 3 data on daridorexant in insomnia at SLEEP 2021

Allschwil, Switzerland – June 9, 2021

Idorsia Ltd (SIX: IDIA) today announced that nine abstracts for daridorexant, the company's investigational dual orexin receptor antagonist for the treatment of adults with insomnia, will be presented at SLEEP 2021. The annual joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society is conducted virtually from June 10-13.

Antonio Olivieri, Senior Vice President, Head of Global Medical Affairs of Idorsia commented:

"As a company with a strong scientific core rooted in innovative small molecules, Idorsia aims to transform the horizon of therapeutic options. We look forward to presenting new data from our Phase 3 clinical program and other important new data on daridorexant. This reflects our commitment to advance research for insomnia, a condition that can substantially impact the physical and mental health of patients and remains an area with great unmet need."

Posters for daridorexant include the following:

- Fietze I, *et al.* Daridorexant is safe and improves both sleep and daytime functioning in elderly patients with insomnia. [347]
- Leger D, *et al.* Absence of Withdrawal Symptoms and Rebound Insomnia Upon Discontinuation of Daridorexant in Patients with Insomnia. [348]
- Zammit G, *et al.* Daridorexant Improves Total Sleep Time (TST) in Insomnia Patients Without Altering the Proportion of Sleep Stages. [344]
- Heidenreich S, *et al.* A benefit-risk assessment of daridorexant for the treatment of insomnia using patient preference data from two phase 3 trials. [343]
- Roch C, *et al.* Daridorexant, a dual orexin receptor antagonist, improves age-related insomnia in rats. [002]
- Bergamini G, *et al.* Effect of the dual orexin receptor antagonist (DORA) daridorexant on behaviour upon awakening in rats and dogs. [09]
- Grandjean CM, *et al.* A dual, equipotent, and insurmountable antagonist of both orexin-1 and orexin-2 receptors. [059]
- Boof ML, *et al.* Daridorexant Does Not Impair Respiratory Function in Patients with Mild/Moderate Obstructive Sleep Apnea Irrespective of Severity. [357]
- Boof ML, *et al.* Daridorexant Improves Sleep in Patients with Mild/Moderate Obstructive Sleep Apnea. [358]

The abstracts can be found in the [SLEEP 2021 Abstract supplement](#).

Daridorexant is currently investigational and is not approved for any use anywhere in the world. In March, the US Food and Drug Administration (FDA) accepted a new drug application (NDA) for review of daridorexant for the treatment of adult patients with insomnia. Idorsia has also submitted marketing authorization applications (MAA) to the European Medicines Agency and Swissmedic for daridorexant for the same indication.

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 is a common problem with a prevalence of approximately 10%. 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 the orexin system

Wake and sleep signalling is regulated by intricate neural circuitry in the brain. One key component of this process is the orexin system, which helps promote wakefulness. There are two forms of orexin neuropeptides – small protein-like molecules used by nerve cells (neurons) to communicate with each other in the brain – orexin A and orexin B. Orexin promotes wakefulness through its receptors OX1R and OX2R. Together, these neuropeptides and receptors make up the orexin system. The orexin system stimulates targeted neurons in the wake system – leading to the release of several chemicals (dopamine, serotonin, histamine, acetylcholine, norepinephrine) which promote wakefulness. Under normal circumstances, orexin levels rise throughout the day as wakefulness is promoted and then fall at night. Overactivity of the wake system is an important driver of insomnia.

About daridorexant

Daridorexant is an investigational dual orexin receptor antagonist (DORA) designed and developed for the treatment of insomnia. Daridorexant reduces overactive wakefulness associated with insomnia by blocking the activity of orexin. DORAs specifically target the orexin system by competitively binding with both receptors, thereby reversibly blocking the activity of orexin. Blocking orexin receptors reduces the downstream activity of the wake-promoting neurotransmitters that are overactive in insomnia.

About the registration program

The Phase 3 registration program comprised two three-month studies, together with a long-term double-blind extension study. Both pivotal studies are complete, having enrolled around 1,850 patients with insomnia at over 160 sites across 18 countries. As insomnia often presents later in life, and elderly patients are more susceptible to fragmented sleep, early awakening and daytime sleepiness, around 40% of the recruited population was aged 65 years or older. The placebo-controlled studies investigated the effects of three doses of daridorexant (10 mg, 25 mg, and 50 mg) on sleep and daytime functioning parameters, objectively in a sleep lab by polysomnography and subjectively with a daily patient diary at home. The impact of insomnia on patients' daytime functioning was measured daily using the sleepiness domain score from the Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ) – a patient-reported outcome (PRO) instrument validated according to FDA industry guidance. Both Phase 3 studies met their primary endpoints and the results were first presented in a late-breaking oral presentation at the Associated Professional Sleep Societies (APSS) SLEEP 2020 medical congress in August 2020.

More than 800 patients continued treatment into a 40-week extension study, which measured the effects of all three doses vs placebo, generating data for long-term treatment of insomnia.



About Idorsia

Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities, and we want to help more patients. In order 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 is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, state-of-the-art facilities, and a strong balance sheet – the ideal constellation to translate R&D efforts into business success.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 900 highly qualified specialists dedicated to realizing our ambitious targets.

For further information, please contact

Andrew C. Weiss

Senior Vice President, Head of Investor Relations & Corporate Communications

Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil

+41 58 844 10 10

investor.relations@idorsia.com

www.idorsia.com

The above information contains certain "forward-looking statements", relating to the company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "are expected to", "will", "will continue", "should", "would be", "seeks", "pending" or "anticipates" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the company's investment and research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company's existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.