



Media Release

August 13, 2020

Daridorexant Phase 3 results in insomnia to be presented at SLEEP 2020

Allschwil, Switzerland – August 13, 2020

Idorsia Ltd (SIX: IDIA) today announced that the positive results from the first pivotal Phase 3 study investigating 25 and 50 mg doses of its dual orexin receptor antagonist, daridorexant, in adult and elderly patients with insomnia, are to be presented at [SLEEP 2020](#). Due to the COVID-19 pandemic, the Associated Professional Sleep Societies (APSS) is turning SLEEP 2020, the world's largest meeting devoted entirely to clinical sleep medicine, and sleep and circadian research, into a virtual meeting from August 27 – 30, 2020. The meeting has live-streamed content as well as on-demand recorded sessions to view.

The abstract entitled “A Phase 3, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Polysomnography Study to Assess Efficacy and Safety of Daridorexant in Adult and Elderly Insomnia Patients” will be presented as an oral presentation by Dr Thomas Roth, PhD, Director of the Sleep Disorder and Research Center at Henry Ford Hospital, and will be available on demand to registered attendees of SLEEP 2020 as part of the late-breaking program.

More information and the late breaking abstract is available in the [Virtual Sleep 2020 meeting guide](#).

The Phase 3 program design will also be presented as a poster entitled “0521 – Daridorexant (ACT-541468), a dual orexin receptor antagonist for the treatment of insomnia disorder: double blind, randomized, Phase 3 studies for efficacy and safety in adult and elderly patients”. The poster will be available on demand to registered attendees of SLEEP 2020 and the abstract can be found in the [Abstract Supplement](#).

In April and July 2020, Idorsia reported positive results in each of the two pivotal Phase 3 studies of daridorexant in patients with insomnia. More details and commentary can be found in the dedicated press releases ([first study release](#)), ([second study release](#)) and the investor webcasts ([first study webcast](#)), ([second study webcast](#)) which are available for replay on the corporate website.

Notes to the editor

About the Phase 3 registration program

The Phase 3 registration program comprises two confirmatory studies of 3-month duration, together with a long-term 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, around 40% of the recruited population was aged 65 years or older. The confirmatory multi-center, double-blind, randomized, placebo-controlled, parallel-group, polysomnography studies investigated 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 the US Food and Drug Administration (FDA) Guidance for Industry. 806 patients decided to continue treatment in the ongoing 40-week extension study which will measure the effect of all three doses vs. placebo, generating data for long-term treatment of insomnia.

About insomnia

Insomnia is defined as a combination of dissatisfaction with sleep and a significant negative impact on daytime performance. 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, worldwide, the most commonly reported sleep disorder and its impact is often underestimated. In reality, it can be a distressing condition that can impair quality of life. Sleepless nights can leave people feeling irritable and out of sorts – this may affect many aspects of daily life, from studying and employment to social activities and relationships. People who suffer from insomnia may lack the energy or motivation to exercise or to take part in social activities. It can also have a significant economic impact as it increases the risk of accident and injury on the road or in the workplace, and is a leading cause of absenteeism and reduced productivity at work. People with insomnia are more likely to experience feeling down or depressed, lack concentration, and suffer from poor energy levels during the day compared with people who sleep well. In addition, worrying about sleep can cause stress and may lead to negative thought patterns which may in turn make it more difficult to sleep, setting up a vicious cycle. Chronic insomnia is associated with cardiovascular and cerebrovascular diseases, and increased mortality.

The goal of treatment for insomnia is to improve sleep quality and quantity, as well as to reduce insomnia-related impaired daytime performance, while avoiding adverse events and next morning residual effects. Current treatment of insomnia includes cognitive behavioral therapy, sleep hygiene recommendations, and pharmacotherapy. The most widely prescribed products on the market that are indicated for insomnia enhance the effects of gamma-aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. Such medications are only approved for short-term use and are associated with side effects such as next-day effects, anterograde amnesia, and risk of tolerance and dependence.

About Dr. Thomas Roth, PhD

Dr. Roth has been the Director of the Sleep Disorders and Research Center at Henry Ford Hospital in Detroit, since 1978. Dr. Roth is also a Professor in the Department of Psychiatry at Wayne State University, School of Medicine in Detroit, Michigan, and serves as a Clinical Professor in the Department of Psychiatry at the University of Michigan, College of Medicine in Ann Arbor.

After serving as president of the Sleep Research Society, and the founding president of the National Sleep Foundation (NSF), Dr. Roth became chairman of the National Center on Sleep Disorders Research advisory board. In addition, he was a member of the board of directors of the Associated Professional Sleep Societies (APSS), chaired the Association's Scientific Program Committee and the governing board of the World Federation of Sleep Research Societies.

Dr. Roth was instrumental in the formation of the Association of Sleep Disorders Center (ASDC) and served as the organization's second president. He is also the former Chairman of the World Health Organization's worldwide project on sleep and health. In addition to authoring and co-authoring numerous articles, Dr. Roth serves as past editor-in-chief of the journal Sleep. He currently sits on the editorial boards of Sleep Reviews, Stress Medicine, and Advances in Therapy and Human Psychopharmacology.

In 2002, Dr. Roth received the NSF's Lifetime Achievement Award for his accomplishments and contributions to sleep science, sleep medicine and public health. He received a Distinguished Research Award from the Sleep Research Society as well as the Nathaniel Kleitman Award from the Academy of Sleep Medicine. Dr. Roth's contributions to the sleep field are expansive, ranging from prolific research productivity and scholarship to multiple national leadership positions, as well as the mentoring of many students and colleagues. Dr. Roth serves as a consultant to Idorsia.

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 one of Europe's leading biopharmaceutical companies, with a strong scientific core.

Headquartered in Switzerland - a biotech-hub of Europe - Idorsia is specialized in the discovery and development of small molecules, to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team, a fully-functional research center, and a strong balance sheet – the ideal constellation to bringing R&D efforts to business success.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 800 highly qualified specialists dedicated to realizing our ambitious targets.

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