Media Release
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Idorsia's daridorexant in women during menopausal transition age with insomnia

- New analysis of a Phase 3 study of daridorexant shows that 50 mg improved both sleep and daytime functioning compared to placebo in women during menopausal transition age
- Brigham and Women's Hospital to study the effectiveness and safety of daridorexant for menopause-related insomnia symptoms

Allschwil, Switzerland – January 5, 2026
Idorsia Ltd (SIX: IDIA) announces the publication of "Efficacy and safety of daridorexant for the treatment of insomnia disorder in women during menopausal transition age: Insights from a randomized controlled trial" in *Maturitas*, a prestigious international journal of midlife health and beyond. This new analysis of the efficacy and safety of daridorexant in women aged 47–55 years with insomnia disorder – a population representative of the menopausal transition – is based on data from the Phase 3 randomized controlled trial (NCT03545191) published in Lancet Neurology and provides important insights into the management of insomnia during in midlife women.

One of the most prevalent and burdensome yet under-researched symptoms reported by women in the menopausal transition is sleep disturbance[1,2]. Multiple factors, including hormonal changes, vasomotor symptoms (e.g. hot flushes, night sweats), psychological changes (e.g. mood symptoms, depression), development of other sleep disorders (e.g. restless legs syndrome, obstructive sleep apnea), and social demands (e.g. caregiving), may contribute, either triggering the onset of or exacerbating preexisting sleep disturbances[3]. Sleep disturbances can have a significant impact on physical and mental health, quality of life, and productivity[4].

Key findings
Daridorexant 50 mg improved both sleep and daytime functioning compared to placebo.
Change from baseline at Month 3:
- Wake after sleep onset (WASO) was improved by ~43 minutes.
- Latency to persistent sleep (LPS) was improved by ~34 minutes.
- Self-reported total sleep time was improved by ~75 minutes.
- Daytime functioning and sleep quality scores were improved.

Furthermore, the incidence of somnolence and fatigue was low and comparable to placebo, and no increase in next-morning sleepiness was observed compared to placebo.

Dr Zoe Schaedel, BMedSci, BMBS, MRCGP, DRCOG, DFSRH, PGCertMedEd, General Practitioner, British Menopause Society (BMS) Menopause Specialist and co-author of the manuscript, commented: "Insomnia disorder affects approximately one in four women during the menopausal transition, yet is often underdiagnosed and certainly undertreated. This analysis shows that daridorexant 50 mg offered meaningful improvements in sleep and daytime functioning without compromising safety. It is essential that clinicians consider the diagnosis of insomnia disorder when sleep disturbances arise during the menopause transition rather than considering it merely secondary to menopausal symptoms, allowing access to evidence-based treatments."

New Brigham and Women's Hospital study

Principal investigators, Dr Bertisch and Dr Redline, from the Brigham and Women's Hospital, a teaching affiliate of Harvard Medical School, have selected daridorexant, Idorsia's dual orexin receptor antagonist (DORA), to be included in a study, CELESTE, focused on menopause-related insomnia. The study will compare the effectiveness and safety of different approaches to treat menopause-related insomnia, including daridorexant as the only pharmacotherapy approved for the treatment of insomnia. Results will help clinicians and their patients when considering ways to treat menopause-related insomnia.

Delivering on the company's commitment to advance the science of sleep and insomnia, Idorsia will be providing daridorexant at no cost, to support this ground-breaking study.

Antonio Olivieri, MD, Chief Medical Officer & Head of Global Medical Affairs at Idorsia commented: "We are excited for daridorexant to be included in this important study, as insomnia is associated with numerous serious health conditions, and is particularly common in women dealing with menopause. Daridorexant works differently from other insomnia medications by decreasing overactive wake signaling, which is a key cause of insomnia. We look forward to seeing the results and continuing to advance the science of insomnia."

About the CELESTE study NCT07136415

Funded by the Patient-Centered Outcomes Research Institute (PCORI), the CELESTE study will include around 900 peri- and post-menopausal women with insomnia. Participants will receive treatment for 12 months and insomnia symptoms will be measured using surveys at the start of the study and again three, six and 12 months later. Treatments, including daridorexant, which is approved by the FDA for adults with insomnia, will be monitored to see if they work differently based on factors such the severity of hot flashes, presence of sleep apnea, and menopause stage. The study will be randomized with daridorexant being one of the three-arm study and is expected to be conducted over a 60-month period.

Global availability of daridorexant

Daridorexant is marketed as QUVIVIQ™ by Idorsia in the US, Canada, and multiple European countries, and is available in Japan, Hong Kong, and China through strategic partnerships.

The daridorexant Phase 3 registration program[5]

The global registration program demonstrated that 25mg and 50mg doses of daridorexant significantly improved sleep onset, sleep maintenance and self-reported total sleep time at months 1 and 3 compared to placebo. A major focus of the trials was to evaluate the impact of daridorexant on daytime functioning in patients with insomnia, as assessed by the IDSIQ. The sleepiness domain score of the IDSIQ was evaluated as a key secondary endpoint in both pivotal studies, and comparisons to placebo included control for multiplicity. Daridorexant 50 mg demonstrated a highly significant improvement in daytime functioning, as measured by the sleepiness domain at month 1 and month 3.

For the US:
Important Safety Information

Do not take QUVIVIQ if you fall asleep often at unexpected times (narcolepsy) or if you are allergic to QUVIVIQ or any of its ingredients.

QUVIVIQ may cause serious side effects, including:

- **Decreased awareness and alertness.** The morning after you take QUVIVIQ, your ability to drive safely and think clearly may be decreased. You may also have sleepiness during the day. Sleepiness may increase your risk of falls.
  - Do not take more QUVIVIQ than prescribed.
  - Do not take QUVIVIQ unless you are able to stay in bed for at least 7 hours before you must be active again.
  - Take QUVIVIQ at night within 30 minutes before going to bed.

QUVIVIQ is a federally controlled substance because it can be abused or lead to dependence.

Before taking QUVIVIQ, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts or actions; drug or alcohol abuse or addiction; a sudden onset of muscle weakness (cataplexy); daytime sleepiness
- have lung or breathing problems, including sleep apnea
- have liver problems
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Taking QUVIVIQ with certain medicines can cause serious side effects. QUVIVIQ may affect the way other medicines work and other medicines may affect the way QUVIVIQ works.
- **Do not take QUVIVIQ with other medicines that can make you sleepy unless instructed by your healthcare provider.**

What should I avoid while taking QUVIVIQ?

- **Do not** drink alcohol while taking QUVIVIQ. It can increase the effects of alcohol, which can be dangerous**.**
- Do not drive, operate heavy machinery, do anything dangerous, or do other activities that require clear thinking if you do not feel fully awake, or you have taken QUVIVIQ and have less than a full night of sleep (at least 7 hours), or if you have taken more QUVIVIQ than prescribed.

QUVIVIQ may cause other serious side effects, including:

- **Worsening depression and suicidal thoughts.** Call your healthcare provider right away if you have any worsening depression or thoughts of suicide or dying**.**
- **Temporary inability to move or talk (sleep paralysis)** for up to several minutes, or hallucinations while you are going to sleep or waking up.
- **Temporary weakness in your legs that can happen during the day or at night**
- **Complex sleep behaviors** such as sleepwalking, sleep-driving, preparing and eating food, making phone calls, having sex or doing other activities while not fully awake that you may not remember the next morning. Stop taking QUVIVIQ and call your healthcare provider right away if you experience a complex sleep behavior.

The most common side effects of QUVIVIQ are headache and sleepiness or tiredness**.**

These are not the only side effects of QUVIVIQ. Call your doctor for advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088

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 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 Dr Zoe Schaedel

Dr Zoe Schaedel, of Myla Health, is an experienced Menopause Specialist. She specialises in women's health, menopause care, sexual health and contraception. She is an accredited specialist with the British Menopause Society (BMS) and is a member of the BMS Medical Advisory Council.

Dr Schaedel contributes to a number of national committees including the NHS England Menopause Improvement Programme and she has delivered talks and masterclasses nationally and to organisations on menopause and on the interplay between menopause, mental health and sleep. She has published articles on menopause in The Lancet and Post Reproductive Health. Dr Schaedel is a trainer for the British Menopause Society and loves to support clinicians who want to further their knowledge on women's health. Dr Schaedel serves as a consultant to Idorsia.

References

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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).

For further information, please contact:

Investor & Media Relations
Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil
+41 58 844 10 10
investor.relations@idorsia.com - media.relations@idorsia.com - www.idorsia.com

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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.