



## Media Release

### May 2, 2022

## Idorsia's new treatment QUVIVIQ (daridorexant) is now available in the US for adults living with insomnia

- In the US, QUVIVIQ™ (daridorexant) CIV 25 mg and 50 mg tablets are indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance<sup>1</sup>
- QUVIVIQ becomes Idorsia's first commercial product in the United States, now available to help American adults who suffer from insomnia

#### **Allschwil, Switzerland & Radnor, PA, US – May 2, 2022**

Idorsia Ltd (SIX: IDIA) & Idorsia Pharmaceuticals, US Inc. today announced that QUVIVIQ™ (daridorexant) CIV 25 mg and 50 mg tablets are now commercially available for adult patients with insomnia, which is characterized by trouble with falling or staying asleep.

Insomnia is a condition of overactive brain activity during sleep, and studies have shown that areas of the brain associated with wakefulness remain more active during sleep in patients with insomnia. Insomnia is the most common sleep disorder, affecting more than 25 million adults in the US.<sup>2</sup> Poor quality or insufficient sleep can affect many aspects of the daily lives of people with trouble sleeping including the ability to concentrate, mood and energy levels.<sup>4</sup> In the long-term, insomnia is associated with numerous serious health conditions, such as psychiatric disorders, cardiovascular disease, substance abuse and dementia.<sup>5,6,7</sup>

QUVIVIQ is a dual orexin receptor antagonist, which blocks the binding of the wake-promoting neuropeptides orexins and is thought to turn down overactive wakefulness in insomnia.<sup>3</sup> QUVIVIQ is recommended once per night, taken orally within 30 minutes before going to bed, with at least seven hours remaining prior to planned awakening.

#### **Patricia Torr, President and General Manager of Idorsia US, commented:**

"After years dedicated to researching the science of sleep and the orexin system, today is a momentous milestone for Idorsia, as the company's first product in the U.S. is now available to patients."

To learn more about QUVIVIQ, visit [QUVIVIQ.com](https://www.quiviviq.com). For more information see the [Full Prescribing Information](#) (PI and Medication Guide).



## About QUVIVIQ

QUVIVIQ is a prescription medicine for adults who have trouble falling asleep or staying asleep (insomnia).

## Important Safety Information

**Do not take QUVIVIQ if you** fall asleep often at unexpected times (narcolepsy).

**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.
  - 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.**
- **Complex sleep behaviors** such as sleep-walking, 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.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Notes to the editor

### About Insomnia

According to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5®), insomnia is defined as a combination of difficulty obtaining sufficient sleep and dissatisfaction with sleep combined with a significant negative impact on daytime functioning. Chronic insomnia is defined as difficulty initiating and/or maintaining sleep on at least three nights per week for at least three months, despite adequate opportunity to sleep.

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Insomnia is the most common sleep disorder, affecting more than 25 million adults in the US.<sup>2</sup> Poor quality or insufficient sleep can affect many aspects of the daily lives of people with trouble sleeping including the ability to concentrate, mood and energy levels.<sup>4</sup> In the long-term, insomnia is associated with numerous serious health conditions, such as psychiatric disorders, cardiovascular disease, type 2 diabetes, substance abuse and dementia.<sup>5,6,7</sup>

### References

1. QUVIVIQ Prescribing Information. Idorsia Pharmaceuticals US Inc. Jan/2022
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### About Idorsia US

Idorsia U.S., an affiliate of Idorsia, is reaching out for more – we have more ideas, we see more opportunities, and we want to help more patients. To achieve this, we will help develop Idorsia into a leading biopharmaceutical company, with a strong scientific core. With commercial operations based outside of Philadelphia, PA, one of densest communities of life sciences talent in the world, we are helping to realize the company's ambition of bringing innovative medicines from bench to bedside. Our goal is to build a commercial footprint that will deliver Idorsia's deep pipeline of products from its R&D engine to the U.S. market – with the potential to change the lives of many patients.

### 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 1,200 highly qualified specialists dedicated to realizing our ambitious targets.

### For further information, please contact

#### US Media

Christopher Clark  
Senior Director, US Head of Communications  
Idorsia Pharmaceuticals US, 100 Matsonford Road, Radnor, PA 19087  
+1 (215) 421 4887  
[christopher.clark@idorsia.com](mailto:christopher.clark@idorsia.com) • [www.idorsia.us](http://www.idorsia.us)



**Global Investors & Media**

Andrew C. Weiss

Senior Vice President, Head of Investor Relations & Corporate Communications

Idorsia Pharmaceuticals Ltd, Hegenheimerweg 91, CH-4123 Allschwil

+41 58 844 10 10

[investor.relations@idorsia.com](mailto:investor.relations@idorsia.com) • [media.relations@idorsia.com](mailto:media.relations@idorsia.com) • [www.idorsia.com](http://www.idorsia.com)

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