



## Media Release

### May 13, 2022

## Idorsia U.S. Announces First Wave of Patients Prescribed QUVIVIQ (daridorexant) through Partnership with Pharmacy Services Provider

### Radnor, PA – May 13, 2022

Following the launch of QUVIVIQ™ (daridorexant) CIV on May 2, Idorsia Pharmaceuticals, U.S. Inc. announced today that the first wave of patients has been prescribed the product through a pharmacy services provider. The pharmacy services provider is working with insurance companies to verify coverage, optimize benefits, explore patient assistance programs, and fulfill valid prescriptions – with the goal of ensuring maximum patient access and lowest out-of-pocket costs. Eligible patients may pay as low as \$0 for the first 30-day prescription of QUVIVIQ and as low as \$25 for each subsequent 30-day refill, complete with home delivery.

QUVIVIQ was approved by the Food and Drug Administration in early January for adults who have trouble falling or staying asleep (insomnia). The product was first commercially available on May 2 through the pharmacy services provider, and all retail pharmacies will be able to order product through their wholesalers starting on May 16.

“We are extremely excited that the first patients in the U.S. have been prescribed QUVIVIQ,” said Patricia Torr, President and General Manager of Idorsia U.S. “After the first week of product availability through our pharmacy services provider partnership, engagement with health care providers and patient adoption trends are very positive and encouraging.”

Insomnia is the most common sleep disorder, affecting more than 25 million adults in the US.<sup>1</sup> Sleep is underrecognized as the third pillar of health, next to diet and exercise, particularly regarding the significant direct consequences it has on our daily lives. The effects of sleep, particularly lack of quality sleep, are felt by people during the day; it impairs health and daily life – from a weakened immune system to challenges with memory and attention.

QUVIVIQ 25mg and 50mg is FDA approved and available for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. 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.<sup>2</sup>

Adults struggling with sleep should speak with their doctor to see if QUVIVIQ is the right treatment option for them. 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 all of the possible side effects of QUVIVIQ. Call your doctor for medical 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

Insomnia is defined as a combination of difficulty obtaining sufficient sleep and dissatisfaction with sleep combined with a significant negative impact on daytime functioning. Insomnia disorder 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.



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.

Significant 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 living with insomnia.

Insomnia as a chronic disorder is different from a brief period of poor sleep, and it can take its toll on both physical and mental health. It can be 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.

#### References

1. Bhaskar S, Hemavathy D, Prasad S. Prevalence of chronic insomnia in adult patients and its correlation with medical comorbidities. *J Family Med Prim Care*. 2016;5(4):780-784. doi:10.4103/2249-4863.201153.
2. QUVIVIQ Prescribing Information. Idorsia Pharmaceuticals US Inc. [01/22]

#### About Idorsia US

Idorsia US, 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 US market – with the potential to change the lives of many patients.

#### For further information, please contact

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