Media Release
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Idorsia Pharmaceuticals Announces Support for a Clinical Trial being Conducted by the U.S. Department of Defense Evaluating QUVIVIQ (daridorexant) as Potential Therapy for Treatment of Posttraumatic Stress Disorder (PTSD)

- Further analysis may evaluate sleep parameters, providing additional information and data about QUVIVIQ in the PTSD population

Radnor, Pa. – May 10, 2023
Idorsia Pharmaceuticals US Inc. announced today its support of a clinical study sponsored by the U.S. Department of Defense (DOD) to develop new therapies to treat Posttraumatic Stress Disorder (PTSD). The Phase 2 multi-center, multi-arm, randomized, placebo-controlled, double-blind, adaptive platform clinical trial will evaluate the safety, tolerability, and efficacy of potential therapeutic interventions in active-duty U.S. service members and veterans with PTSD. This clinical trial will include QUVIVIQ® (daridorexant) CIV, a medicine approved by the FDA for the treatment of adults with difficulty falling or staying asleep (insomnia), and at least two other FDA-approved medications for the treatment of depression, all of which will be studied under an Investigational New Drug application for the treatment of PTSD. QUVIVIQ is a dual orexin receptor antagonist (DORA) that was approved in 2022 in the United States and the European Union, and it is the only FDA-approved insomnia medication being evaluated in this study.

The clinical trial is expected to enroll its first subject in Q2 2023, and the QUVIVIQ arm of the study is forecast to run for approximately three years. Study endpoints for each medication will be measured after twelve weeks of treatment and compared to pooled placebo, with the primary endpoints being validated endpoints that measure PTSD symptom severity, and secondary endpoints measuring insomnia and other medical conditions. Complete trial details are available here: https://www.clinicaltrials.gov/ct2/show/NCT05422612.

“This innovative clinical trial and public-private partnership addresses the need for safe and effective therapies to treat PTSD in our current and former servicemen and women, as well as the general population,” said Dr. Kimberly del Carmen, the DOD’s PTSD Drug Treatment Program Product Manager at the U.S. Army Medical Materiel Development Activity (USAMMDA) at Fort Detrick, Maryland. USAMMDA is working on behalf of the Defense Health Agency to administer the trial. “We’ll efficiently test multiple potential treatments for PTSD and significantly contribute to the development of new safe and effective therapies.”

In the U.S., QUVIVIQ was approved by the FDA in January 2022 for the treatment of adults who have trouble falling asleep or staying asleep (insomnia).[1] It is a dual orexin receptor antagonist, which blocks the binding of the wake-promoting neuropeptide orexin, which is thought to turn down overactive wake signaling, in contrast to many other insomnia medications that cause a sedative effect on the central nervous system. Idorsia is supporting this clinical trial by providing study drug and placebo to DOD as well as access to the validated measurement tool, Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ).

For more information about QUVIVIQ, see the **Full Prescribing Information** and **Medication Guide**

Important Safety Information

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

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 or call 1-800-FDA-108

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.

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.[6] 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.[2] 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.[3,4,5]

About PTSD

PTSD is a chronic and disabling psychiatric disorder with a lifetime prevalence of approximately 7% in the US. PTSD is characterized by intrusive thoughts, nightmares and flashbacks of past traumatic events, avoidance of reminders of trauma, hypervigilance, and sleep disturbance, all of which lead to considerable social, occupational, and interpersonal dysfunction.

While patients suffering from PTSD all exhibit some element of the cardinal features as defined by the DSM-5, there is significant heterogeneity in clinical presentation. Certain symptoms may be more prominent in some patients than others, and most patients have at least 1 additional psychiatric comorbidity such as insomnia, depressive disorders, anxiety disorders, or substance use disorders.

PTSD symptoms can persist for years or decades after the traumatic event; only one-third of patients recovered at the 1-year follow-up and one-third remained symptomatic 10 years later.[8] PTSD is associated with poor social support, higher healthcare utilization, and may be associated with increased mortality.[9]

References

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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.

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 1'000 highly qualified specialists dedicated to realizing our ambitious targets.

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