

MIRA Pharmaceuticals Designates Neuropathic Pain as Primary Indication for Ketamir-2 and Submits Pre-IND Meeting Request to FDA

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MIAMI, FL / ACCESSWIRE / September 11, 2024 / MIRA Pharmaceuticals, Inc. (NASDAQ:MIRA), a preclinical-stage pharmaceutical company focused on developing innovative therapies for neurologic and neuropsychiatric disorders, announced today that it has selected neuropathic pain as the initial and primary indication for its novel oral ketamine analog, Ketamir-2. The company has submitted a request for a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) and anticipates the meeting to occur in November 2024. All ongoing regulatory IND-enabling studies are advancing smoothly, and MIRA remains on track to submit its IND to the FDA by the end of this year, with human trials expected to begin in the first quarter of 2025.

The Growing Neuropathic Pain Market

Neuropathic pain is a complex and debilitating condition caused by a variety of causes, induced by damage or dysfunction of the nervous system. It often presents as burning, electric shocks, or "pins and needles" sensations, significantly impacting the quality of life for millions of patients. The North American market for neuropathic pain treatments is projected to grow to approximately \$5.2 billion across the U.S., Canada, and Mexico by 2030, driven by rising prevalence rates, an aging population, and the increasing burden of diseases such as diabetes and chemotherapy-induced neuropathy ([Databridgemarketresearch.com](https://www.databridgemarketresearch.com)).

Current treatment options for neuropathic pain, including antidepressants, anticonvulsants, topical agents, and opioids, often provide limited relief and include significant side effects. For example, antidepressants and anticonvulsants can cause dizziness, weight gain, and sedation, while opioids carry risks of addiction, tolerance, and withdrawal. The opioid crisis alone is costing the United States approximately \$1 trillion annually, a stark reminder

of the devastating consequences of opioid misuse, recently underscored by the tragic death of actor Matthew Perry, who had openly struggled with addiction (**Congressman David Trone**).

Ketamir-2: Positioned to Transform Neuropathic Pain Management

Ketamir-2 is MIRA's response to this pressing market need—a novel ketamine analog designed to enhance therapeutic efficacy, improve oral bioavailability, and offer a superior safety profile compared to existing treatments. Unlike traditional ketamine, which has poor oral bioavailability and a higher risk of side effects, Ketamir-2 is engineered as a low-affinity NMDA receptor antagonist that selectively binds to the phencyclidine (PCP) site, delivering more consistent pain relief with fewer adverse effects.

What sets Ketamir-2 apart from other current neuropathic pain treatments is its unique profile: it is not an opioid, does not share the dependency risks associated with opioids, and is classified as a non-controlled substance by the U.S. Drug Enforcement Administration. This distinction allows Ketamir-2 to be more accessible and less regulated, broadening its potential use in clinical settings. Moreover, Ketamir-2's oral administration as a pill makes it a convenient option compared to more invasive or cumbersome treatments like infusions or patches.

Preclinical studies have demonstrated that Ketamir-2 surpasses traditional ketamine by providing safe and effective pain relief without the sedative effects commonly seen with ketamine therapy. These findings position Ketamir-2 as a strong candidate to address the significant unmet needs in central nervous system (CNS) disorders.

Strategic Focus on Neuropathic Pain and Future Indications

Selecting neuropathic pain as the primary indication for Ketamir-2 underscores MIRA's commitment to addressing a significant and growing market. Additional studies that further highlighting its versatility and strategic value are planned. These studies will explore Ketamir-2's potential in treating various forms of neuropathic pain such as diabetic neuropathy as well as cancer-and cancer-therapy-induced neuropathic pain.

"We see a tremendous opportunity to address the unmet needs in the neuropathic pain market, which is poised to grow substantially over the next decade," said Erez Aminov, Chairman and CEO of MIRA. "Ketamir-2's novel mechanism of action, non-opioid classification, and promising safety profile position it as a breakthrough solution that could redefine pain management for millions of patients."

Dr. Angel, Chief Scientific Advisor of MIRA, added, "Our smooth and effective progress with Ketamir-2 IND-enabling studies has been highly encouraging, particularly in its broad-spectrum potential to treat both neuropathic pain and depression. Developing a safe, effective, and convenient oral treatment for these challenging conditions represents a transformative advancement in pain management. We are eager to advance towards human trials and bring this

much-needed therapy to patients."

About MIRA Pharmaceuticals, Inc

MIRA Pharmaceuticals, Inc. (NASDAQ:MIRA) is a pre-clinical-stage pharmaceutical development company with two neuroscience programs targeting a broad range of neurologic and neuropsychiatric disorders. MIRA holds the exclusive U.S., Canadian, and Mexican rights for Ketamir-2, a novel, patent-pending oral ketamine analog under investigation to treat neuropathic pain (NP), treatment-resistant depression (TRD), major depressive disorder with suicidal ideation (MDD-SI), and post-traumatic stress disorder (PTSD).

MIRA's novel oral pharmaceutical marijuana analog, MIRA-55, is currently under investigation for treating adult patients suffering from anxiety and cognitive decline, often associated with early-stage dementia. If approved by the FDA, MIRA-55 could mark a significant advancement in addressing various neuropsychiatric, inflammatory, and neurologic diseases and disorders.

The U.S. Drug Enforcement Administration's scientific review concluded that both Ketamir-2 and MIRA-55 would not be considered controlled substances or listed chemicals under the Controlled Substances Act and its governing regulations.

Additional information about MIRA Pharmaceuticals is available at: www.mirapharmaceuticals.com.

Cautionary Note Regarding Forward-Looking Statements

This press release and the statements of MIRA Pharmaceuticals' (or the "Company") management related thereto contain "forward-looking statements," which are statements other than historical facts made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any statements in this press release that are not historical facts may be deemed forward-looking. These forward-looking statements include, without limitation, statements regarding the anticipated benefits of the study results described herein as well as the timing for the Company's other preclinical studies and the filing of an IND for Ketamir-2. Any forward-looking statements in this press release are based on the Company's current expectations, estimates, and projections only as of the date of this release and are subject to a number of risks and uncertainties (many of which are beyond the Company's control) that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These and other risks concerning the Company's programs and operations are described in additional detail in the Annual Report on

Form 10-K for the year ended December 31, 2023, and other SEC filings, which are on file with the SEC at www.sec.gov and the Company's website at <https://www.mirapharmaceuticals.com/investors/sec-filings>. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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