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Lohocla Research Announces FDA Clearance of Investigational New Drug Application for Kindolor, a Novel Medicinal Molecule for Treating Chronic Pain

Focusing on non-addictive treatments for chronic pain and addiction, Lohocla Research Corporation gets the go-ahead for first-in-human trials of their first-in-class therapeutic for chronic pain syndromes.

Aurora, Colorado, 31 October 2023 – **Lohocla Research Corporation** today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application, enabling the company to proceed with Phase 1 trials for **Kindolor**. Kindolor is Lohocla's first-in-class, non-addicting small molecule that treats as well as prevents the development of chronic pain disorders. Lohocla will begin first-in-human trials in the first quarter of 2024.

Acknowledging the promise of this new drug, the National Institutes of Health (NIH) has committed substantial funding through the National Institute on Drug Abuse (NIDA) and the Helping to End Addiction Long-term® (HEAL) Initiative for researching the safety and effectiveness of this innovative, rationally designed molecule.[i]

Company **Founder and CEO Boris Tabakoff**, Ph.D. said, "The breakthrough was the design of a molecule that addresses four important biological targets that act as generators of chronic pain without affecting other targets. We have demonstrated that this approach results in a very effective medication that could truly work as a substitute for – or adjunct to – opiates and could reduce opiate use severalfold."

About Chronic Pain

Over 100 million adults in the U.S. suffer from intermittent or constant chronic pain. Moreover, chronic pain affects at least 10 percent of the world's population. The primary pharmaceuticals for treatment of chronic pain have been natural or synthetic opioids, which have resulted in what has been called an "epidemic" of opioid abuse, addiction, and lethal overdoses.[ii] This crisis is fueled by the lack of good alternatives to opiates for treating chronic pain.

About Kindolor

Dr. Tabakoff was a pioneer in introducing the concept of "Network Pharmacology" to the development of medications for treating and preventing chronic pain. He realized that chronic pain conditions are

not the result of a malfunction in some single target, such as a receptor or an enzyme, and consequently will not respond well to drugs that are designed to modify the action of one particular entity or target. Instead, chronic pain is a failure of a biological network of several, interconnected elements, requiring a multi-target drug to rectify the network failure. In response, Lohocla Research set about using rational drug design techniques to construct a molecule that modulates – simultaneously – four key elements of the chronic-pain network. The choice of these targets was based upon the fact that they are uniquely positioned in series within pain sensory systems, leading to focused action on the cells that initiate pain. The result of this design effort was Kindolor.

Kindolor has exhibited all necessary characteristics indicating its effectiveness and safety in treating chronic pain. In pre-clinical studies, Kindolor was shown to reverse chronic pain in six different models, including models of diabetic neuropathy, chronic pain due to traumatic nerve injury, chronic pain induced by exposure to cancer-treatment drugs, and chronic pain generated by inflammation. In all of these models, it was the uncontrollable, excessive pain that was eliminated, while the normal pain reflex remained intact. Accordingly, Kindolor controls chronic pain without numbing normal, protective sensation of acute pain. In a multitude of studies on metabolism and safety, Kindolor demonstrated a good safety profile. Moreover, Kindolor does not enter the brain to any extent and its actions, as predicted, are confined to the peripheral sensory nerves. This specificity for the peripheral nervous system helps to explain why Kindolor does not display sedation, development of tolerance, or liability for addiction. Additionally, not only is Kindolor able to ease chronic pain on its own, but it can also be employed to substantially reduce the use of opiates, thereby mitigating the risk of opiate abuse and overdose.

About Lohocla Research

At Lohocla Research Corporation, we work towards one goal: developing pharmaceutical innovations that improve people's lives. Understanding the challenges of chronic pain and addiction, we focus on transforming the lives of patients suffering from these conditions. Built upon a rationally designed, proprietary molecular platform, we have developed a first-of-its-kind molecule that selectively modulates a discrete set of receptors involved in the chronic pain signaling pathway in overactive peripheral nerves as well as a pioneering drug for the treatment of alcohol use disorder, addiction, and craving.

Phonetic pronunciation: low-HOE-kluh

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[ii] https://www.cdc.gov/drugoverdose/epidemic/index.html

Public Health Relevance Statement

The U.S. and other countries around the world are facing "dual crises of pain and opioid addiction." Lohocla Research Corporation has responded to the opioid crisis and medication development challenge by designing, synthesizing, and demonstrating, in pre-clinical studies, the efficacy and safety of a non-opiate, non-addictive new chemical entity (NCE) for treatment of chronic pain. This NCE, called Kindolor, has significant additional benefits of being able to prevent the development of chronic pain if administered soon after tissue injury, including post-operative conditions. Kindolor also has a highly significant "opiate sparing" effect in conditions that may require the use of opiates, since Kindolor demonstrates a strong synergistic effect with morphine. With FDA approval, we will complete first-in-human, Phase I clinical studies for safety and Phase 2a studies of efficacy to bring our medication to chronic pain sufferers.