



## **Proniras Corporation Announces First Patient Enrolled in Phase 1 Clinical Trial for Opioid Withdrawal Syndrome**

*PRN-001-01 (tezampanel) is a novel antagonist of glutaminergic signaling  
with potential to suppress opiate withdrawal symptoms*

*First-in-human study to evaluate the safety, tolerability, PK profile, and efficacy  
in patients with Opioid Use Disorder*

*Dosing of first patient represents key advancement in Proniras' clinical pipeline*

**November 14, 2024, Seattle** – Proniras Corporation (“Proniras”), a clinical-stage biotechnology company developing novel small-molecule therapeutics for the treatment of substance use and specialty central nervous system disorders, today announced that the first patient has been dosed in the Phase 1 clinical trial evaluating its lead compound, PRN-001-01 (tezampanel) as a therapy for patients recovering from opioid addiction and related conditions. PRN-001-01 (tezampanel) is a competitive antagonist with selectivity for the AMPA and kainate subtypes of the ionotropic glutamate receptor family.

The Phase 1 trial is being conducted at Indiana University (IU) School of Medicine and is designed to evaluate the safety, tolerability, pharmacokinetics, and efficacy of PRN-001-01 (tezampanel) in the treatment of opioid withdrawal syndrome. The trial is anticipated to enroll approximately 40 patients with Opioid Use Disorder (OUD). The study will also provide insights into the effectiveness of blocking glutamate receptors to alleviate withdrawal symptoms, utilizing the Clinicians Assessment of Opiate Withdrawal Severity (COWS) and related measures. The results may show that PRN-001-01 (tezampanel) can relieve patients from withdrawal symptoms, potentially alleviating a crucial impediment in progression to long-term sobriety. Additional information about the study is available at [clinicaltrials.gov \(NCT06538558\)](https://clinicaltrials.gov/NCT06538558).

“Treating the first patient is a significant milestone for Proniras as we seek to address the needs of underserved patients suffering from opioid use disorder,” said Thong Q. Le, CEO of Proniras and Senior Managing Director of Accelerator Life Science Partners. “Supported by encouraging preclinical results, the Phase 1 clinical trial will formally assess the potential of tezampanel to make a meaningful difference for people suffering the symptoms of opioid withdrawal syndrome. This debilitating set of symptoms traps individuals and thwarts their attempts to escape dependence on opioids.”

“Understanding the role of glutamate pathways in addiction has been a significant area of research, and tezampanel is the first glutamate antagonist to enter investigational use for opioid use disorders,” said R. Andrew Chambers, MD, Professor of Psychiatry and Director of Addiction Psychiatry Training at IU School of Medicine. “IU School of Medicine is well-positioned to spearhead the effort to evaluate tezampanel’s impact on opioid withdrawal syndrome, given the devastating impact of the opioid crisis in the American Midwest. We are excited to have the first patient enrolled in this initial trial.”

## **About Opioid Withdrawal Syndrome**

Opioid Withdrawal Syndrome is a psychologically and physically punishing condition that occurs when a person who has developed a physical dependence on opioids suddenly stops or significantly reduces their use of opioids. It is characterized by a range of uncomfortable symptoms including anxiety, agitation, muscle aches, sweating, nausea, vomiting, diarrhea, and intense drug cravings. Opioid withdrawal can be severe, often thwarting the best intentions of individuals striving for an opiate-free life. The syndrome affects a significant number of people. A recent assessment (2020-2024) of opioid withdrawal syndrome in the developed world reported annual case rates of approximately 8 million, with 85% occurring in the United States—an alarming statistic expected to persist over the next decade.

## **About Proniras Corporation**

Proniras Corporation is a clinical-stage biotechnology company dedicated to developing novel small-molecule therapeutics for the treatment of substance use disorders and specialty central nervous system conditions. Leveraging cutting-edge research and innovative approaches, Proniras aims to address the unmet medical needs of patients suffering from these challenging conditions. The company's lead compound, PRN-001-01 (tezampanel), is a novel antagonist of glutaminergic signaling that is currently in a Phase 1 clinical trial for the treatment of opioid withdrawal syndrome and other related disorders. Proniras is committed to improving patient outcomes and enhancing the quality of life through pioneering scientific breakthroughs. Proniras was founded in 2017 by Accelerator Life Science Partners. For more information, please visit [www.proniras.com](http://www.proniras.com).

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