

Novamigra Tx Announces Successful Pre-IND Meeting with FDA, Paving the Way for Accelerated Clinical Development

Novamigra Tx Announces Successful Pre-IND Meeting with FDA for Migraine Prophylaxis Asset VRG-145, Paving Way for Accelerated Clinical Development

BUDAPEST, HUNGARY, January 14, 2025 /EINPresswire.com/ -- Novamigra Tx, a pioneering biopharmaceutical company dedicated to transforming migraine therapy, announces the successful completion of its pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA). This milestone marks a significant step in the clinical development of Novamigra Tx's lead asset, VRG-145.

FDA Supports Accelerated Clinical Development Strategy

During the pre-IND meeting, the FDA provided highly encouraging feedback, endorsing Novamigra Tx's proposed clinical development strategy. The agency confirmed that no additional non-clinical studies are required before advancing, reflecting confidence in the robustness of Novamigra Tx's preclinical data. Furthermore, the FDA approved initiating clinical trials with a combined Phase 1b/2a study, eliminating the need for a traditional Phase 1 trial. This positive guidance positions Novamigra Tx to progress rapidly. After completing Chemistry, Manufacturing, and Controls (CMC) development, the company plans to submit its IND and anticipates the first patient dosing as early as Q1 2026.

Advancing Toward Transformative Migraine Therapy

VRG-145 represents a first-in-class therapeutic approach, distinct from existing treatments such as antiepileptics, beta-blockers, calcium channel blockers, certain antidepressants, and CGRP antagonists. By leveraging a unique mechanism of action that targets both the vascular and neuronal pathways underlying migraines, VRG-145 aims to fill critical gaps in preventive migraine management.

This innovation offers hope for the 40–50% of patients who remain resistant to current therapies, addressing a pressing unmet need in migraine treatment.

Next Steps and Call for Strategic Partners

In preparation for clinical trials, Novamigra Tx is finalizing CMC activities and plans to submit its

IND by Q3 2025. The company is actively seeking strategic financial partners to support this critical phase. With one investor already committed, Novamigra Tx is on track to generate human Proof-of-Concept (PoC) data by Q4 2026 - a key milestone in making this innovative therapy widely accessible to patients.

About Novamigra Tx

Novamigra Tx, a spin-out venture of VRG Therapeutics, is a forward-thinking pharmaceutical company that delivers groundbreaking therapy for migraine prophylaxis. The company is committed to innovation and patient-centric solutions, striving to address the unmet need for more effective and tolerable migraine treatments through a novel mechanism of action.

About Migraine Prophylaxis

Migraine affects approximately one billion people worldwide, with an estimated 40% requiring preventive treatment. The global migraine prophylaxis market is projected to reach \$10 billion by 2027, growing at a compound annual growth rate (CAGR) of 9.4% according to Nature Reviews. Despite this demand, current therapies often provide only moderate efficacy, poor tolerability, and high resistance rates. Approximately 50% of patients achieve less than a 50% reduction in migraine frequency, underscoring the critical need for more effective and innovative solutions.

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