



Vaxxinity Announces First Subjects Dosed in Phase 1 Clinical Trial of UB-313 for Preventive Treatment of Migraine

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DALLAS, Sept. 13, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced that the first subjects have been dosed in a Phase 1 clinical trial of UB-313, a vaccine targeting calcitonin gene-related peptide (CGRP), for the preventive treatment of migraine.

"Initiating this first-in-human study of UB-313 represents another milestone for Vaxxinity as we continue to expand our clinical pipeline into chronic conditions using our unique peptide vaccine platform," said Mei Mei Hu, Chief Executive Officer of Vaxxinity. "An anti-CGRP vaccine has the potential to disrupt the migraine paradigm by offering longer-lasting relief, more convenient administration, and affordable access. Our vision is to help migraine patients worldwide reclaim their lives with UB-313."

Jan de Hoon, M.D., Professor in Pharmacology and Clinical Pharmacology, KU Leuven in Belgium, and principal investigator, commented: "Therapeutics targeting the CGRP pathway have been identified as an effective treatment option for chronic and episodic migraines. Following the success of monoclonal antibodies for the prevention of migraine and small molecule CGRP-receptor antagonists for migraine prevention and acute treatment, an immunotherapeutic vaccine could bring about a transformational third wave of options for patients."

The Phase 1 randomized, placebo-controlled, double-blind, multidose trial will enroll approximately 40 healthy volunteers at the Center for Clinical Pharmacology, UZ Leuven in Belgium. The objectives of the trial are to evaluate safety, tolerability, and immunogenicity. Immunogenicity will be measured by serum anti-CGRP antibody titers. Pharmacodynamics of the immune response will be measured by the inhibition of capsaicin-induced increase in dermal blood flow, an established model of target engagement in migraine.

More information about the trial is available at clinicaltrials.gov using Identifier [NCT05477095](https://clinicaltrials.gov/ct2/show/study/NCT05477095).

About UB-313

UB-313 is a novel immunotherapeutic vaccine candidate targeting calcitonin gene-related peptide (CGRP) for the preventive treatment of migraine. CGRP causes vasodilation and neurogenic inflammation, and is known to play an important role in migraine pathophysiology. UB-313 is designed to trigger the production of antibodies that inhibit CGRP in patients with chronic and episodic migraine in order to reduce migraine frequency and severity. Preclinically, UB-313 has shown strong immunogenicity across species, inducing anti-CGRP antibodies with similar properties as approved comparator monoclonal antibodies, as well as a favorable safety and tolerability profile. This trial was granted approval by the Federal Agency for Medicines and Health Products (FAMHP) in Belgium.

About Migraine

Migraine is a chronic and debilitating disorder often characterized by a unilateral headache accompanied by a cluster of autonomic and neurologic symptoms. It has been identified as the sixth most prevalent disorder and one of the main causes of disability worldwide, often occurring in young adults and middle-aged women.¹ The pathophysiology of migraine is complex, including changes in the vasculature, central and peripheral pain processing, and inflammation. CGRP is known to play an important role in migraine pathophysiology. Raised levels of CGRP are observed both peripherally and centrally in migraine patients. Multiple CGRP-targeting therapies have been approved for the treatment and prevention of migraine.

About Vaxxinity

Vaxxinity, Inc. is a purpose-driven biotechnology company committed to democratizing healthcare across the globe. The company is pioneering a new class of synthetic, peptide-based immunotherapeutic vaccines aimed at disrupting the existing treatment paradigm for chronic disease, increasingly dominated by monoclonal antibodies, which suffer from prohibitive costs and cumbersome administration. The company's proprietary technology platform has enabled the innovation of novel pipeline candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer's, Parkinson's, migraine, and hypercholesterolemia. The technology is also implemented as part of a COVID-19 vaccine program. Vaxxinity has optimized its pipeline to achieve a potentially historic, global impact on human health.

For more information about Vaxxinity, Inc., visit <http://www.vaxxinity.com> and follow us on social media @vaxxinity.

Forward-looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "potential," "vision," "may," "could," "will" and similar expressions, are intended to identify forward-looking statements. These forward-looking statements involve substantial risks and uncertainties, and are based on the current expectations and assumptions of Vaxxinity's management. Forward-looking statements include statements about the future development of immunotherapeutic vaccines and the innovation and efficacy of Vaxxinity's product candidates. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements. Additional important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022 and other reports we file with the Securities and Exchange Commission. The forward-looking statements are made as of this date and Vaxxinity does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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¹ World Health Organization. (2016, April 8). *Headache disorders*. <https://www.who.int/news-room/fact-sheets/detail/headache-disorders>