VistaGen Therapeutics Announces Positive Meeting with FDA Regarding Pivotal Phase 3 Study of PH94B for Acute Treatment of Anxiety in Patients with Social Anxiety Disorder

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Company Reaches Consensus with FDA on Key Aspects of Novel Pivotal Phase 3 Study

Agency Guidance May Provide Significant Time- and Cost-Efficiency for Phase 3 Program

Approximately 17 Million American Adults Suffer from Social Anxiety Disorder

SOUTH SAN FRANCISCO, Calif., July 23, 2020 /PRNewswire/ -- VistaGen Therapeutics (NASDAQ: VTGN), a biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) disorders, announced the results of a positive meeting with the U.S. Food and Drug Administration (FDA) regarding Phase 3 development of PH94B for the acute treatment of anxiety in adult patients with social anxiety disorder (SAD).

VistaGen and the FDA reached consensus on key aspects of a unique initial pivotal Phase 3 clinical trial of PH94B involving a single-event, laboratory-simulated public speaking challenge in adult patients with SAD.

PH94B is an investigational rapid-onset neurosteroid nasal spray that is fundamentally differentiated from all FDA-approved treatments for anxiety disorders. According to the U.S. National Institute of Mental Health (NIMH), there are approximately 17 million adults in the U.S. with SAD.

"Much like a rescue inhaler is used in an asthma attack or a migraine drug is used in an acute migraine episode, PH94B is a potential fit for the acute treatment of anxiety symptoms in anticipation of an often predictable, anxiety-provoking situation for individuals suffering from SAD," said Shawn Singh, Chief Executive Officer of VistaGen.

"Notably, the FDA concurred that our initial pivotal Phase 3 efficacy study may be conducted in a manner substantially similar to the highly statistically significant Phase 2 study of PH94B, which study involved a single event, laboratory-simulated public speaking challenge in adult patients with SAD. The FDA's specific guidance will enable us to simplify the process of assessing efficacy among SAD patients in our Phase 3 studies and contribute to significant time- and cost-efficiency in the clinic," Singh added.

Key Aspects of Consensus with FDA Regarding the Initial Pivotal Phase 3 Study of PH94B

VistaGen's initial pivotal Phase 3 study of PH94B for acute treatment of anxiety in adult patients with SAD will be a randomized, double-blind, placebo-controlled, parallel comparison study conducted at approximately 12 to 15 sites in North America.

Dr. Michael Liebowitz, Professor of Clinical Psychiatry at Columbia University, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale (LSAS), will be the Principal Investigator of the study. Target enrollment will be approximately 182 adult patients with SAD.

As in the successful Phase 2 study of PH94B in SAD, the study will involve a single laboratory-simulated anxiety-provoking public speaking challenge. The Subjective Units of Distress Scale (SUDS) will be used to assess the primary efficacy endpoint in the study.

About PH94B

PH94B is a first-in-class, odorless, rapid-onset (within approximately 15 minutes) synthetic neurosteroid nasal spray with therapeutic potential across a broad range of anxiety-related disorders. Easily self-administered in microgram-level doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects.

VistaGen is preparing for Phase 3 clinical development of PH94B as a potential new generation fast-acting, non-sedating, non-addictive acute treatment of anxiety in adults with social anxiety disorder (SAD). The FDA has granted Fast Track designation for development of PH94B for this indication, the first such designation by the FDA for a drug candidate for SAD.

With its rapid-onset pharmacology, lack of systemic exposure and excellent safety profile in earlier studies, PH94B has potential as a novel treatment for multiple anxiety-related disorders. VistaGen is also preparing for Phase 2A development of PH94B for adjustment disorder related to the diverse impact of the COVID-19 pandemic. View more background information on SAD and a video on PH94B's mechanism of action.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and certain CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. Each of VistaGen's three drug candidates has a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in several large global CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects, including the potential for successful New Drug Application (NDA)-enabling Phase 3 development of PH94B. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: development and approval of PH94B may not be achieved in any market; the FDA may decide that the results of the Company's PH94B Phase 3 clinical program are not sufficient for regulatory approval for acute treatment of anxiety in adult patients with SAD or any other anxiety-related disorder; development of PH94B may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed in future studies which may not support further development or be sufficient to gain regulatory approval to market PH94B; adverse events may be encountered at any stage of development that negatively impact further development. Other risks and uncertainties include, but are not limited to, issues related to: adverse healthcare reforms and changes of laws and regulations; general industry and market conditions; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B; inadequate and/or untimely supply of PH94B to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B, as well as those risks more fully discussed in the section entitled "Risk Factors" in VistaGen's most recent Annual Report on Form 10-K for the year ended March 31, 2020, as well as discussions of potential risks, uncertainties, and other important factors in either company's other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today, and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

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