VistaGen Therapeutics Further Advances PALISADE Phase 3 Program for PH94B in Social Anxiety Disorder with Initiation of PALISADE-2

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PALISADE Phase 3 Program focused on PH94B's potential as a rapid-onset, acute treatment of anxiety in adults with social anxiety disorder

SOUTH SAN FRANCISCO, Calif., Sept. 13, 2021 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system ("CNS") disorders, today announced the initiation of PALISADE-2, the second U.S. Phase 3 clinical trial to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with social anxiety disorder ("SAD"). PH94B is designed to be an odorless, rapid-onset pherine nasal spray with a unique potential mechanism of action for the acute treatment of anxiety in adults with SAD, working differently than all therapies approved by the U.S. Food and Drug Administration (the "FDA") indicated for SAD.

PALISADE-2 is a randomized, multi-center, double-blind, placebo-controlled clinical trial that is a replicate of VistaGen's ongoing PALISADE-1 trial of PH94B for the acute treatment of anxiety in adults with SAD. Both studies are designed in a manner that is substantially similar to the public speaking component of a peer-reviewed published Phase 2 study of PH94B for the acute treatment of anxiety in adults with SAD. In that Phase 2 study, PH94B was observed to have rapid reduction in anxiety (within 15 minutes) in response to a public speaking challenge (p=0.002). PALISADE-2 will be conducted across approximately 15 clinical sites in the United States, with a target of approximately 208 patients. Dr. Michael Liebowitz, a Columbia University psychiatrist, former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale, is serving as principal investigator of the trial. Topline results from PALISADE-1 and PALISADE-2 are anticipated in mid-2022 and in the second half of 2022, respectively.

"Following the successful initiation of PALISADE-1 last quarter, we are excited to be further advancing our PALISADE Phase 3 Program this quarter with the initiation of PALISADE-2, an essential next step in our efforts to further demonstrate the reduction in anxiety observed in PH94B's Phase 2 clinical trials to date," stated Shawn Singh, Chief Executive Officer of VistaGen. "If successful, these Phase 3 clinical trials, along with the other planned clinical trials in our PALISADE Phase 3 Program, are intended to support the potential submission of a New Drug Application to the FDA in 2023. Our team continues to make progress towards that core objective. PH94B has the potential to be a life-changing acute, as-needed treatment of anxiety for adults with SAD, similar to how a rescue inhaler is used on demand to acutely treat an asthma attack."

PALISADE Phase 3 Program for PH94B

VistaGen's PALISADE Phase 3 Program is designed to further demonstrate the potential of PH94B as a fast-acting, acute treatment of anxiety in adults with SAD. If successful, upon completion of the PALISADE Phase 3 Program, VistaGen plans to submit a New Drug Application to the FDA for PH94B for the acute treatment of anxiety in adults with SAD. PALISADE-1 and PALISADE-2 are replicate U.S., multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trials designed to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. PALISADE-1 and PALISADE-2 were initiated in May 2021 and September 2021, respectively.

About Social Anxiety Disorder (SAD)

Social anxiety disorder affects as many as 23.7 million Americans and, according to the National Institutes of Health, is the third most common psychiatric condition after depression and substance use. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a question in class, or talking to a cashier in a store. Doing common, everyday things in front of people causes profound anxiety or fear of being humiliated, evaluated, judged, or rejected. SAD can get in the way of going to work, attending school, or doing a wide variety of things in a situation that has the potential for interpersonal interaction. It can lead to avoidance and opportunity cost that can significantly impact a person's employment and social activities and be very disruptive to overall quality of life. SAD is commonly treated chronically with certain FDA-approved antidepressants, which have a slow onset of effect (several weeks) and limited therapeutic benefits, and benzodiazepines, which are not FDA-approved for treatment of SAD but are prescribed for off-label use. Both antidepressants and benzodiazepines have known side effects and safety concerns that may make them unattractive to individuals affected by SAD.

About PH94B

PH94B is a first-in-class, odorless, rapid-onset (approximately 15 minutes), pherine nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand treatment for millions of Americans who suffer from SAD, with the potential to also treat adjustment disorder, postpartum anxiety, procedural anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Administered at microgram doses, PH94B activates nasal chemosensory neurons that trigger neural circuits in the brain that suppress fear and anxiety. Following successful completion of PH94B's Phase 2 development, VistaGen initiated its PALISADE-1 and PALISADE-2 Phase 3 clinical trials of PH94B for the acute treatment of anxiety in adults with SAD. The FDA has granted Fast Track designation for the development of PH94B for the acute treatment of anxiety in adults with SAD.

About VistaGen Therapeutics

VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression and other CNS disorders. Each of VistaGen's drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple 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 Phase 3 development of PH94B for the acute treatment of anxiety in adults with SAD. 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: completion of PALISADE-1 and/or PALISADE-2 may be delayed due to a variety of factors, including factors related to the ongoing COVID-19 pandemic; development and approval of PH94B may not be achieved in any market; the FDA may decide that the results of PALISADE-1 and PALISADE-2 and other studies in VistaGen's PALISADE PH94B Phase 3 Program are not sufficient to support a New Drug Application, or for regulatory approval for the acute treatment of anxiety in adults 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 at any time during the PALISADE Phase 3 Program, including during PALISADE-1 or PALISADE-2, or future trials, which trials may not support further development or be sufficient to gain regulatory approval to market PH94B; and 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 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, 2021, and in its most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 as well as discussions of potential risks, uncertainties, and other important factors in its other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent VistaGen's views only as of today and should not be relied upon as representing its views as of any subsequent date. VistaGen explicitly disclaims any obligation to update any forward-looking statements.

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