VistaGen Expands PH94B Clinical Development to Include Adjustment Disorder Related to COVID-19

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Proposed Phase 2 Study to Take Place in New York City Under U.S. FDA's Coronavirus Treatment Acceleration Program (CTAP)

SOUTH SAN FRANCISCO, Calif., April 28, 2020 /PRNewswire/ -- VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) diseases and disorders with high unmet medical need, today announced plans to expand clinical development of PH94B, its first-in-class rapid-onset neuroactive nasal spray, to include treatment of adjustment disorder due to stressors related to the COVID-19 pandemic. Adjustment disorder is an emotional or behavioral reaction considered excessive or out of proportion to a stressful event or major life change, occurring within three months of the stressor, and/or significantly impairing a person's social, occupational and/or other important areas of functioning.

VistaGen plans to submit its proposed protocol for a Phase 2 study of PH94B for treatment of adjustment disorder to the U.S. Food and Drug Administration (FDA) through the FDA's new Coronavirus Treatment Acceleration Program (CTAP). The proposed Phase 2 Part A study will be conducted in New York City, the epicenter of the COVID-19 pandemic in the U.S., on an open-label basis and involve approximately 30 subjects suffering from adjustment disorder from stressors related to the pandemic. Based on the results of the Phase 2 Part A study, VistaGen plans to advance development to a Phase 2 Part B randomized, double-blind, placebo-controlled study of approximately 150 subjects. The FDA previously designated PH94B for Fast Track development for treatment of social anxiety disorder (SAD), the first such designation by the FDA for a drug candidate for SAD. VistaGen is currently preparing for Phase 3 development of PH94B for treatment of SAD.

Dr. Michael Liebowitz, a member of VistaGen's CNS Clinical and Regulatory Advisory Board, will serve as Principal Investigator of the Phase 2 Part A study of PH94B for treatment of adjustment disorder. Dr. Liebowitz is a Professor of Clinical Psychiatry at Columbia University and directs the Medical Research Network LLC in New York City. He directed the Anxiety Disorders Clinic at the New York State Psychiatric Institute from 1982 to 2006 and is also creator of the Liebowitz Social Anxiety Scale, or LSAS, a widely used primary outcome measure in clinical research on SAD, as well as for evaluation in clinical practice.

"The COVID-19 pandemic has created fear, anxiety and uncertainty about our health and the economy that have caused mental health challenges worldwide," said Shawn Singh, Chief Executive Officer of VistaGen. "After the immediate medical threats associated with COVID-19 pass, the pandemic is expected to have a lasting impact on millions of people. With increases in anxiety-related disorders to be expected, the need for new, fast-acting and safe treatment alternatives is greater now than ever before. With its exceptional safety profile and positive data from Phase 2 development for treatment of social anxiety disorder, PH94B has significant potential to make a meaningful difference across the treatment landscape for multiple anxiety-related disorders."

"Mental health-related disorders have escalated and continue to be overwhelmingly underserved indications as a result of the current crisis," concluded Dr. Liebowitz. "Today, more than ever, I am concerned over the suffering of those who are experiencing debilitating, heightened symptoms of adjustment disorder and anxiety as a result of the COVID-19 pandemic – and how those individuals are coping and receiving treatment. The alternatives in the market, both prescribed and not prescribed, have significant limitations in efficacy and problematic side effects. We need better alternative treatments as we approach a vastly different social environment in the near future."

About VistaGen
VistaGen Therapeutics is a multi-asset, 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. VistaGen's pipeline is focused on

clinical-stage CNS drug candidates with a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

About PH94B
PH94B is a first-in-class, odorless, rapid-onset (approximately 10 to 15 minutes) CNS neuroactive nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand treatment for millions of Americans who suffer from social anxiety disorder (SAD), with additional potential in adjustment disorder, peripartum anxiety, pre/postoperative anxiety or anxiety related to certain testing such as an MRI, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Administered at microgram doses, PH94B activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety. Following successful Phase 2 development, VistaGen is preparing for Phase 3 clinical development of PH94B for SAD and Phase 2 development for adjustment disorder. The FDA has granted Fast Track designation for development of PH94B as a treatment for SAD. View more background on SAD and PH94B's mechanism of action.

About Adjustment Disorder
According to the DSM-5, published by the American Psychiatric Association, adjustment disorder is the development of emotional or behavioral symptoms in response to an identifiable stressor(s) occurring within 3 months of the onset of the stressor(s). These symptoms or behaviors are clinically significant, as evidenced by one or both of the following: marked distress that is out of proportion to the severity or intensity of the stressor, considering the external context and the cultural factors that might influence symptom severity and presentation; or significant impairment in social, occupational, or other important areas of functioning. The stress-related disturbance does not represent normal bereavement or meet the criteria for another mental disorder and is not merely an exacerbation of a preexisting mental disorder.

About the U.S. FDA Coronavirus Treatment Acceleration Program
FDA has created a special emergency program for possible therapies called the Coronavirus Treatment Acceleration Program (CTAP). The FDA's CTAP uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. The FDA continues to support clinical trials that are testing new treatments for COVID so that it gains valuable knowledge about their safety and effectiveness.

To learn more about Coronavirus Treatment Acceleration Program (CTAP), please use the following link: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

Forward-Looking Statements
This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of PH94B for adjustment disorder, social anxiety disorder and other anxiety disorders, including the Company's expectation that its planned submission to the FDA regarding its proposed Phase 2 Part A clinical development of PH94B for treatment of adjustment disorder will qualify for expedited review under the FDA's CTAP. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Those risks include the following: (i) we may encounter unexpected adverse events in patients during our clinical development of any product candidate that cause us to discontinue further development; (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development; (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market PH94B; (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates; (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates; (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing preclinical and clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of PH94B and/or our other product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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