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VistaGen Submits PH94B Phase 2A Study Protocol for Treatment of Adjustment Disorder with Anxiety Related to the COVID-19 Pandemic through U.S. FDA's Coronavirus Treatment Acceleration Program (CTAP)

The Proposed Phase 2A Open-label Study will be Conducted in New York City

SOUTH SAN FRANCISCO, Calif., May 18, 2020 /PRNewswire/ -- [VistaGen Therapeutics](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for anxiety and depression, as well as certain central nervous system (CNS) diseases and disorders with high unmet medical need, today announced that the Company has submitted its proposed protocol for a Phase 2A study of PH94B, its investigational anti-anxiety drug, for treatment of adjustment disorder with anxiety related to the COVID-19 pandemic to the U.S. Food and Drug Administration (FDA) through the FDA's new Coronavirus Treatment Acceleration Program (CTAP). Adjustment disorder is an emotional or behavioral reaction considered excessive or disproportionate 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.



"The recent onset of mental health stressors associated with the COVID-19 pandemic is unprecedented and has affected nearly every person around the world," said Shawn Singh, Chief Executive Officer of VistaGen. "We strongly believe in PH94B's potential as a first-in-class, rapid-onset anti-anxiety drug, without systemic exposure or safety concerns of current anti-anxiety drugs. With successful Phase 2 development of PH94B for social anxiety disorder completed and preparations for Phase 3 development underway, we now look forward to Phase 2 development of PH94B for adjustment disorder, with the goal of achieving similarly positive treatment outcomes for individuals struggling to cope with difficulties related to COVID-19, as well as a wide range of other anxiety-provoking mental health stressors."

The proposed Phase 2A 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 patients suffering from adjustment disorder with anxiety from stressors related to the pandemic. Dr. Michael Liebowitz, a member of VistaGen's CNS Clinical and Regulatory Advisory Board, Professor of Clinical Psychiatry at Columbia University and director of the Medical Research Network in New York City, will serve as Principal Investigator.

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 three clinical-stage CNS drug candidates, each 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 therapeutic potential across a broad range of anxiety-related disorders, including social anxiety disorder (SAD), adjustment disorder with anxiety (AjDA), peripartum anxiety, pre/postoperative or testing (e.g., MRI) anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Self-administered as a nasal spray at microgram doses, PH94B activates chemosensory receptors in the nasal passage

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 2A development for AjDA associated with the COVID-19 pandemic. The FDA has granted Fast Track designation for development of PH94B as a treatment for SAD, the first such designation by the FDA for SAD. [View more background on SAD and a video on PH94B's mechanism of action.](#)

About Adjustment Disorder with Anxiety

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), adjustment disorder is the development of emotional or behavioral symptoms in response to an identifiable stressor occurring within 3 months of the onset of the stressor. 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 (CTAP)

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-19 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 with anxiety (AjDA), social anxiety disorder and other anxiety-related disorders, including the Company's expectation that its submission to the FDA regarding its proposed Phase 2A clinical study protocol for PH94B for treatment of AjDA related to the COVID-19 pandemic 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 in 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 the substantial additional capital necessary to support our operations, including our ongoing and/or planned preclinical and/or clinical development studies; and (vii) we may encounter technical and other unexpected hurdles and delays in the manufacturing and development of any of our 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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