VistaGen to Present PH94B Exploratory Phase 2A Research Program for Adjustment Disorder with Anxiety at American Society for Clinical Psychopharmacology Annual Meeting

June 2, 2022

SOUTH SAN FRANCISCO--(BUSINESS WIRE)--Jun. 2, 2022-- VistaGen Therapeutics, Inc. (Nasdaq: VTGN) (VistaGen), a late clinical-stage, central nervous system (CNS)-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders, today announced that the clinical trial abstract for its exploratory Phase 2A clinical study in adjustment disorder with anxiety (AjDA) for PH94B, its investigational rapid-onset pherine nasal spray with potential to treat multiple anxiety disorders, was accepted by the American Society for Clinical Psychopharmacology (ASCP) for the 2022 ASCP Annual Meeting taking place May 31 through June 3, 2022.

The clinical trial abstract for the Company's ongoing exploratory Phase 2A clinical trial, entitled " **Efficacy, safety, and tolerability of PH94B in adjustment disorder with anxiety: design of an exploratory phase 2A clinical trial**," describes the clinical trial protocol intended to evaluate PH94B's potential to treat adults living with AjDA, a disorder with potential for increased prevalence during these uncertain times. PH94B is a first-in-class, odorless, tasteless rapid-onset (approximately 15 minutes) investigational pherine nasal spray with a novel mechanism of action (MOA) that regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system. VistaGen is also currently evaluating PH94B in the Company's two PALISADE Phase 3 clinical trials for the acute treatment of anxiety in adults with social anxiety disorder (SAD).

"Mental health challenges are accelerating in communities across America. Patients and healthcare providers are seeking better solutions to the growing prevalence of anxiety and depression, and VistaGen is working hard to develop innovative solutions," said Shawn Singh, Chief Executive Officer of VistaGen. "There is significant demand and need for treatments for anxiety disorders, including adjustment disorder. At this important moment and amid this significant unmet need, we look forward to sharing our clinical trial abstract with top psychopharmacology leaders in attendance at the ASCP Annual Meeting."

The ASCP Annual Meeting is the premiere meeting each year in the field of psychopharmacology and brings together over 800 academic and industry investigators, research pharmacists, and clinicians, the National Institutes of Health (NIH), Food and Drug Administration (FDA), and European regulatory agencies to discuss key aspects of neuropsychiatric drug development. In recent years, the ASCP Annual Meeting focus has been expanded to address a number of timely issues relevant to clinical research in psychiatry, including the translation of research into practice, the importance of regulatory issues, and pharmacogenetics and other means to personalizing interventions.

About PH94B
VistaGen's PH94B is a first-in-class, odorless, tasteless rapid-onset (approximately 15 minutes) investigational pherine nasal spray with a novel mechanism of action (MOA) that regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system. Based on positive Phase 2 data in social anxiety disorder (SAD) patients, VistaGen is currently evaluating PH94B in two Phase 3 clinical studies in the U.S., PALISADE-1 and PALISADE-2, and a long-term safety study, for the acute treatment of anxiety in adults with SAD. Designed for intranasal administration in low microgram doses, the novel MOA of PH94B is fundamentally differentiated from all current anti-anxiety medications, including benzodiazepines. VistaGen's proposed MOA for PH94B does not involve either direct activation of GABA-A receptors or binding to neuronal receptors in the CNS. Rather, PH94B's proposed MOA involves binding to peripheral chemosensory neurons in the nasal passages to regulate the olfactory-amygdala fear and anxiety neural circuits. Both clinical and preclinical data suggest that PH94B has the potential to achieve rapid-onset anti-anxiety effects without systemic uptake or transport into the brain, reducing the risk of benzodiazepine-like side effects and other safety concerns. In addition to SAD, for which the FDA has granted Fast Track designation, PH94B may have potential in adjustment disorder with anxiety, procedural anxiety, PTSD, postpartum anxiety and panic disorder.

About Adjustment Disorder with Anxiety
Almost everyone experiences significant life events, changes, or stressors from time to time, and while some individuals adjust to such changes within a few months, others cannot and may experience adjustment disorder. Adjustment disorder with anxiety (AjDA) is the development of emotional or behavioral symptoms considered excessive or disproportionate in response to a sudden change, stressful event or circumstance, or other identifiable anxiety-provoking stressor, such as loss of work, divorce or a health setback, that significantly impairs a person's social, occupational and/or other important area(s) of functioning.

About VistaGen
VistaGen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company striving to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. VistaGen's clinical-stage candidates are targeting multiple forms of anxiety and depression. They belong to a new class of drugs known as pherines, which are odorless, neuroactive steroids that bind to distinct receptors on chemosensory neurons in the nasal passages and can impact the limbic amygdala without systemic uptake or direct activity on CNS neurons in the brain. VistaGen's lead candidate, PH94B, is a nasally administered spray currently in multiple Phase 3 trials in the U.S., with results anticipated in 2022. Should ongoing Phase 3 studies be successful, PH94B has the potential to be the first FDA-approved, fast-acting, acute treatment of anxiety for adults with social anxiety disorder. VistaGen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. Connect at www.VistaGen.com.

Forward Looking Statements
This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements

involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by VistaGen and its management, are inherently uncertain. The Company's actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching, conducting and/or completing ongoing and planned clinical trials, including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of the Company's CNS drug candidates due to the ongoing COVID-19 pandemic or otherwise; inadequate and/or untimely supply of one or more of the Company's CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2021 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2021, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). The Company's SEC filings are available on the SEC's website at www.sec.gov . You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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