Vistagen Announces Completion of Last Patient, Last Visit in Phase 2 Clinical Trial of PH94B for the Treatment of Adjustment Disorder with Anxiety

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Topline results of the exploratory Phase 2 clinical study anticipated in Q1 2023

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jan. 10, 2023-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other central nervous system (CNS) disorders, today announced that the last patient has completed the study protocol in its Phase 2 clinical trial of PH94B for the treatment of adults experiencing adjustment disorder with anxiety (AjDA).

The exploratory Phase 2 clinical trial is a U.S. multi-center, randomized, double-blind, placebo-controlled study intended to evaluate efficacy, safety and tolerability of PH94B administered four times per day over four weeks for the treatment adjustment disorder with anxiety symptoms in adults. The primary endpoint is the change from baseline in anxiety level as measured by the Hamilton Anxiety Rating Scale (HAM-A) at the end of Week 4 of treatment with PH94B or placebo. Dr. Michael Liebowitz, a former Columbia University psychiatrist, founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute, and currently director of the Medical Research Network in New York City, is serving as Principal Investigator of the trial. Topline results are anticipated at the end of Q1 2023.

“The four-week treatment protocol for our final enrolled patient is complete. This is a major milestone for our team,” stated Shawn Singh, Chief Executive Officer of Vistagen. “Along with many other mental health challenges, the prevalence of adjustment disorder is alarming due to increasing levels of health, safety, economic and social stressors that adversely impact mental health and wellbeing. Vistagen is dedicated to developing treatments to address the escalating mental health crisis. We look forward to completing data analysis for this important study over the coming months.”

About PH94B

Vistagen’s PH94B is a first-in-class, rapid-onset investigational pherine nasal spray with a novel proposed 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, without systemic distribution, potentiation of GABA-A or direct activity on CNS neurons in the brain. Vistagen is developing PH94B in a Phase 3 program for the treatment of social anxiety disorder and in an exploratory Phase 2 development program for the treatment of adjustment disorder with anxiety. Designed for intranasal administration in low microgram doses, the proposed novel MOA of PH94B is fundamentally differentiated from all currently approved anti-anxiety medications, including all antidepressants and benzodiazepines.

About Adjustment Disorder

Adjustment disorder (AjD) refers to a maladaptive emotional or behavioral response to an identifiable stressor. AjD occurs within three months of exposure to the stressor as evidenced by marked distress that is out of proportion to the socially or culturally expected reactions to the stressor, or that represents significant impairment in social, occupational or other important areas of daily functioning. A Mental Health Surveillance Study estimated prevalence of adjustment disorder at 7% in the U.S. adult population, or about 18 million adults in the U.S, in 2022. Current pharmacological treatments for AjD vary widely. Current treatments include antidepressants, benzodiazepines and buspirone, among others.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming 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. PH94B and PH10 belong to a new class of drugs known as pherines, which are investigational neuroactive steroid nasal sprays designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic uptake or direct activity on CNS neurons in the brain. 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. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or developments may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company’s drug candidates, including PH94B and/or PH10, or any other pherine drug candidate will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. These risks, along with additional risks, are 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, 2022 and in the Company’s most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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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