VistaGen Announces Topline Results from PALISADE-1 Phase 3 Clinical Trial for Investigational Drug PH94B

July 22, 2022

PH94B for Acute Treatment of Social Anxiety Disorder Did Not Meet Primary Endpoint

PH94B Showed a Favorable Safety and Tolerability Profile among Study Participants that was Consistent with Prior Clinical Trial Results

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 22, 2022-- VistaGen Therapeutics, Inc. (Nasdaq: VTGN) (VistaGen, the Company), 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 topline results from its PALISADE-1 Phase 3 clinical trial of PH94B for the acute treatment of anxiety in adults with social anxiety disorder. PH94B did not achieve its primary endpoint, as measured by change from baseline using the Subjective Units of Distress Scale (SUDS) compared to placebo. Although the trial did not meet its primary endpoint, the tolerability profile of PH94B in PALISADE-1 was favorable and consistent with previously reported results from all other clinical trials. No severe or serious adverse events were reported for PH94B in prior clinical trials or in PALISADE-1.

“The demand for new treatment options for anxiety disorders is large and growing. While the results of PALISADE-1 are not consistent with prior positive results from Phase 2 trials of PH94B in social anxiety disorder, we remain committed to transforming the treatment landscape for those living with anxiety, depression, and other central nervous system disorders,” said Shawn Singh, Chief Executive Officer of VistaGen. “As part of this commitment, our team will continue to pursue PH94B’s potential as a new treatment option for multiple anxiety disorders — including for both acute treatment for social anxiety disorder in our ongoing PALISADE-2 Phase 3 trial and for continued use in our ongoing Phase 2 trial in adjustment disorder with anxiety. We would like to thank the patients and investigators for their participation in the trial, and we will continue to evaluate the detailed data from PALISADE-1 as we move forward with our ongoing trials.”

PALISADE-1 was a multi-center, randomized, double-blind, placebo-controlled, parallel design, Phase 3 clinical study in adults diagnosed with social anxiety disorder (SAD). The study was designed to evaluate the efficacy, safety, and tolerability of the acute administration of PH94B to relieve symptoms of anxiety in adult patients with SAD during a simulated public speaking challenge, measured using the patient-reported SUDS. Prior to the public speaking challenge, the subjects were randomized to receive a single dose of PH94B or placebo.

VistaGen has three drug candidates in its CNS pipeline, PH94B, PH10 and AV-101, with the potential to go beyond the current standard of care for anxiety, depression and other CNS disorders. Each of the Company’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.

About Social Anxiety Disorder

Social anxiety disorder (SAD) affects an estimated 25 million Americans. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, making comments in a business meeting, 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 may cause profound anxiety or fear of being embarrassed, evaluated, humiliated, 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 is likely to involve interpersonal interaction. It can lead to avoidance and opportunity costs that can significantly impact a person's employment and social activities and be very disruptive to their overall quality of life. SAD is commonly treated long-term with certain FDA-approved antidepressants, which have a slow onset of effect (several weeks) and provide limited therapeutic benefits, and benzodiazepines, which are not FDA-approved for the treatment of SAD. Both antidepressants and benzodiazepines have known side effects and significant safety concerns that may make them unattractive to individuals affected by SAD.

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. VistaGen’s CNS pipeline includes three CNS drug candidates, PH94B, PH10 and AV-101, with the potential to go beyond the current standard of care for CNS indications with high unmet need. Each of the Company’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. PH94B is a first-in-class investigational pherine nasal spray in Phase 3 development for the acute treatment of anxiety in adults with social anxiety disorder and in Phase 2 development for adjustment disorder with anxiety. VistaGen is also considering PH94B for clinical development in additional acute (on-demand) and continued use anxiety disorders, including procedural anxiety, panic disorder, postpartum anxiety and post-traumatic stress disorder. PH10 is an investigational pherine nasal spray in clinical development as a stand-alone treatment for major depressive disorder and potentially multiple other depression-related disorders. AV-101 is an investigational oral prodrug of 7-chloro-kynurenic acid (7-Cl-KYNA), a potent and selective full antagonist of the glycine co-agonist site of the NMDAR, in clinical development with potential to become a new oral treatment alternative for certain CNS indications involving the NMDAR. 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 any pharmaceutical product, 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 PH94B or any of the Company's other drug candidates will receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the results of the Company's PALISADE-1 Phase 3 clinical trial reported in this press release; the completion and results of the Company's ongoing clinical studies of PH94B, including the PALISADE-2 Phase 3 clinical trial and the Company's Phase 2A clinical trial of PH94B in adults experiencing adjustment disorder with anxiety; delays in launching, conducting and/or completing other 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; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates. These risks are 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, 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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