Vistagen to Present Fasedienol (PH94B) Safety and Exploratory Efficacy Data from Phase 3 Open-Label Social Anxiety Disorder Study at American Society for Clinical Psychopharmacology Annual Meeting

May 30, 2023

Late-breaking poster presentation highlights long-term, open-label treatment data of as-needed intranasal administrations of fasedienol in real-world setting

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 30, 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 safety and exploratory efficacy data from its Phase 3 open-label study of fasedienol (PH94B) nasal spray for the treatment of adults with social anxiety disorder (SAD) will be presented in a late-breaking poster presentation at the American Society for Clinical Psychopharmacology (ASCP) 2023 Annual Meeting taking place in Miami from May 30 through June 2, 2023.

Poster Session I: Wednesday, May 31, 2023, 11:15 a.m. to 1:00 p.m. Eastern Time
Title: A Phase 3 Open-label Safety Trial of Fasedienol (PH94B) Nasal Spray in the Treatment of Anxiety in Adults With Social Anxiety Disorder (SAD)
Poster Number: W74

The poster will be available at https://www.vistagen.com/publication after the conclusion of the conference.

About Fasedienol (PH94B)

Vistagen's fasedienol (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 receptors or direct activity on neurons in the brain. Vistagen is developing fasedienol in a Phase 3 program for the treatment of social anxiety disorder. Designed for intranasal administration in low microgram doses, the proposed novel MOA of fasedienol is fundamentally differentiated from all currently approved anti-anxiety medications, including all antidepressants and benzodiazepines.

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 causes 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 can 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 with benzodiazepines, which are not FDA-approved for treating 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 biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. Vistagen is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available for treatment of anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes six clinical-stage product candidates, including five investigational agents belonging to a new class of drugs known as pherines, in addition to AV-101, an oral antagonist of the glycine site of the N-methyl-D-aspartate receptor (NMDAR). Pherines, which are administered as nasal sprays, are designed with an innovative rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can selectively and beneficially impact key neural circuits in the brain without requiring systemic uptake or direct activity on CNS neurons. Vistagen's AV-101 inhibits activity of the ion channel of the NMDAR but does not block it. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety, depression and several other CNS disorders. Connect at www.Vistagen.com.

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