Vistagen Initiates PALISADE-4 Phase 3 Study of Fasedienol for the Acute Treatment of Social Anxiety Disorder

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Next step in registration-directed PALISADE Phase 3 program for fasedienol in social anxiety disorder achieved as planned

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 23, 2024-- Vistagen (Nasdaq: VTGN) a late clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on nose-to-brain neurocircuitry, today announced enrollment of the first subject in its PALISADE-4 Phase 3 trial of fasedienol, an investigational neuroactive pherine nasal spray in U.S. registration-directed Phase 3 development for the acute treatment of social anxiety disorder (SAD).

"With the initiation of PALISADE-4 as planned, we have achieved another important milestone in our registration-directed PALISADE Phase 3 program for fasedienol, which has potential to deliver a transformative acute treatment option to over 30 million Americans suffering from the debilitating effects of SAD, including increased risk for depression, alcohol abuse, and suicide attempts," said Shawn Singh, Chief Executive Officer of Vistagen. "Current pharmacological therapies approved by the U.S. FDA do not include an acute treatment option. With pioneering neuroscience, we are breaking new ground in the development of a treatment for SAD with our novel product candidate designed for non-systemic, rapid activation of nose-to-brain neural circuits to reduce fear and anxiety associated with SAD."

About Vistagen's PALISADE Phase 3 Program for Fasedienol for the Acute Treatment of SAD

Vistagen's U.S. registration-directed PALISADE Phase 3 development program for fasedienol for the acute treatment of SAD includes the ongoing PALISADE-3 and PALISADE-4 Phase 3 trials, each a randomized, double-blind, placebo-controlled Phase 3 trial designed to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in subjects with SAD induced by a public speaking challenge conducted in a clinical setting. PALISADE-3 and PALISADE-4 are designed similarly to Vistagen's PALISADE-2 Phase 3 trial of fasedienol, from which positive data was reported last year. The primary outcome measure in each of the PALISADE Phase 3 trials is a subject's self-rated Subjective Units of Distress Scale (SUDS). Similar to PALISADE-3 initiated earlier this year, the PALISADE-4 Phase 3 U.S. multi-center trial is planned to randomize approximately 236 adults aged 18 through 65. Subjects will be randomized in a 1:1 ratio to fasedienol or placebo. PALISADE-3 and PALISADE-4 also include open-label extension phases to evaluate the safety and tolerability of ongoing use of fasedienol in a real-world setting over a period of up to 12 months. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the FDA for the acute treatment of SAD.

About Fasedienol Nasal Spray

Fasedienol is a potential first-in-class, investigational neuroactive pherine nasal spray designed to have rapid onset with a novel proposed mechanism of action (MOA) that is differentiated from all currently approved anxiety medications. Fasedienol is designed to regulate the olfactory-amygdala neural circuits of fear and anxiety and attenuate the tone of the sympathetic autonomic nervous system, without systemic absorption, potentiation of GABA-A receptors, or direct activity on neurons in the brain. Vistagen's U.S. registration-directed PALISADE Phase 3 program for fasedienol is focused on the acute treatment of SAD. Fasedienol has not demonstrated any signals of abuse potential or suggested any potential for psychological and physical dependence in any clinical trial conducted to date. There is no U.S. FDA-approved acute treatment for SAD. The U.S. FDA has granted Fast Track designation for the investigation of fasedienol for the acute treatment of SAD.

About Social Anxiety Disorder

Social anxiety disorder (SAD) affects over 30 million Americans. A person with SAD feels intense, persistent, and sometimes disabling 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 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. There is no U.S. FDA-approved acute treatment for SAD.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on its pioneering approach and deep understanding of nose-to-brain neurocircuitry. Vistagen's diversified pipeline of pherine product candidates is designed exclusively as nasal sprays administered at microgram level doses to rapidly activate chemosensory neurons in the nasal cavity with novel non-systemic proposed mechanisms of action designed to impact the olfactory system and brain neurocircuitry to achieve diverse therapeutic effects. Favorable safety data have been generated in all clinical studies of Vistagen's pherine product candidates completed to date. Vistagen's neuroscience pipeline also includes an oral prodrug with the potential to modulate NMDA receptor activity in certain neurological conditions, such as levodopa-induced dyskinesia associated with Parkinson's disease therapy and neuropathic pain. At Vistagen, we are passionate about creating novel and differentiated treatments that set new standards of care for millions of people living with anxiety, depression, and other neurological disorders. 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 Vistagen's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful, or that Vistagen will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, itruvone, PH80 or its other drug candidates. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including PALISADE-3 and/or PALISADE-4; launching planned clinical trials for any of our product candidates, including fasedienol; Vistagen's submission of a new drug application (NDA) to the U.S. FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by the Company to the U.S. FDA to support a NDA; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct Vistagen'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 Vistagen's product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in Vistagen's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2024, and Quarterly Report on Form 10-Q for the period ended June 30, 2024, 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). Vistagen'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 Vistagen's views as of any subsequent date. Vistagen explicitly disclaims any obligation to update any forward-looking statements other than as may be required by law. If Vistagen does update one or more forward-looking statements, no inference should be made that Vistagen will make additional updates with respect to those or other forward-looking statements.

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