Vistagen on Track to Deliver Topline Data From Fasedienol PALISADE-3 Phase 3 Trial for Acute Treatment of Social Anxiety Disorder in the Fourth Quarter of This Year

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Company's PALISADE-4 Phase 3 trial now expected to read out in the first half of 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 2, 2025-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry to develop and commercialize a new class of intranasal product candidates called pherines, today provides an update on the timeline for the ongoing clinical trials in its U.S. registration-directed PALISADE Phase 3 Program evaluating fasedienol for acute treatment of social anxiety disorder (SAD). The Company's PALISADE-3 Phase 3 clinical trial remains on track for expected topline data in the fourth quarter of this year. Topline results for its PALISADE-4 Phase 3 clinical trial are expected in the first half of 2026.

"We are very encouraged by the progress of our PALISADE-3 trial, which remains on track for a topline readout in the fourth quarter of this year, and our PALISADE-4 trial, for which we expect topline results in the first half of 2026," said Shawn Singh, President and Chief Executive Officer of Vistagen. "Patient and physician enthusiasm for our PALISADE trials continues to be strong, and we remain focused on meticulous patient recruitment. With social anxiety affecting millions and rising, we are energized by fasedienol's potential to meet the clear and growing unmet need and bring meaningful relief to patients, all while delivering long-term value to shareholders."

Vistagen reported positive results from its PALISADE-2 Phase 3 trial of fasedienol for acute treatment of SAD in 2023. The Company's ongoing PALISADE-3 and PALISADE-4 Phase 3 trials involve the same public speaking challenge study design as its successful PALISADE-2 Phase 3 trial, as well as certain protocol and operational enhancements related to site training, surveillance and subject selection. These strategic enhancements, which have extended certain timelines in the PALISADE Phase 3 program, were designed with the objective of replicating the success of PALISADE-2. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.

About Social Anxiety Disorder

Social anxiety disorder (SAD) is a highly prevalent, serious, and sometimes life-threatening psychiatric mental health disorder affecting over 30 million adults in the U.S. With onset typically early in life, usually during adolescence, SAD persists for many years thereafter, with a reported mean duration of about 20 years. While often a long-term disorder, SAD can manifest acutely when triggered by anxiety-provoking social and performance situations during which individuals with SAD experience extreme anxiety, distress, fear, and impairment due to their feelings of embarrassment, judgment, humiliation, negative evaluation, and scrutiny. The disorder can significantly disrupt family and social life, diminish self-esteem, and hinder work performance. Anxiety associated with SAD often results in avoidance of everyday interactions and opportunities in academic, social, and vocational settings and an increased risk of serious and life-threatening co-morbid depression, substance abuse, suicidal ideation, and suicide.

About Fasedienol Nasal Spray for the Acute Treatment of Social Anxiety Disorder

Fasedienol is Vistagen's potential first-in-class, investigational neurocircuitry-focused pherine nasal spray designed to have rapid onset with a novel 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 binding to neurons in the brain. The U.S. FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of SAD.

About Vistagen's U.S. Registration-directed PALISADE Phase 3 Program for Acute Treatment of Social Anxiety Disorder

The ongoing clinical trials in Vistagen's U.S. registration-directed PALISADE Phase 3 Program for fasedienol for the acute treatment of SAD include its PALISADE-3 and PALISADE-4 Phase 3 trials and a small Phase 2 repeat dose study, which is being conducted at the FDA's request to further elucidate fasedienol's dose response and MOA. PALISADE-3 and PALISADE-4 are multi-center, randomized, double-blind, placebo-controlled Phase 3 trials designed similarly to PALISADE-2 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 remains on track for topline data in the fourth quarter of 2025. Topline results for PALISADE-4 and the repeat dose study are expected in the first half of 2026. Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol New Drug Application (NDA) submission to the U.S. FDA for the acute treatment of SAD.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company leveraging a deep understanding of nose-to-brain neurocircuitry to develop and commercialize a broad and diverse pipeline of clinical-stage product candidates from a new class of intranasal therapies called pherines. Pherines specifically and selectively bind as agonists to peripheral receptors on human nasal chemosensory neurons, and are designed to rapidly activate olfactory bulb-to-brain neurocircuits believed to regulate brain areas involved in behavior and autonomic nervous system activity. They are designed to achieve therapeutic benefits without requiring absorption into the blood or uptake into the brain, giving them the potential to be a safer alternative to other pharmacological options. Vistagen's neuroscience pipeline also includes an oral prodrug with potential to impact certain neurological conditions involving the NMDA receptor.

Vistagen is passionate about developing transformative treatment options to improve the lives of individuals underserved by the current standard of care for multiple highly prevalent indications, including social anxiety disorder, major depressive disorder, and multiple women's health conditions, including vasomotor symptoms (hot flashes) associated with menopause. 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. There can be no guarantee that any of Vistagen's product candidates, including fasedienol, will successfully complete ongoing or future clinical trials within estimated timelines or at all, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to conducting and/or completing ongoing clinical trials, including that are a part of Vistagen's PALISADE Phase 3 program, as currently expected or at all; submission of a NDA to the U.S. FDA for any of Vistagen's product candidate, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the U.S. FDA to successfully support a NDA; Vistagen's dependence on third-party collaborators for the development, regulatory approval, and/or commercialization of its product candidates and other aspects of its business, which are outside of Vistagen's full control; risks associated with current and potential future healthcare reforms; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine product 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 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 December 31, 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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