Vistagen Completes PALISADE-3 Phase 3 Public Speaking Challenge Study for the Acute Treatment of Social Anxiety Disorder

November 3, 2025

Topline results for the trial are expected by year end

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--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 announced that the last patient has completed the randomized, double-blind, placebo-controlled portion of the PALISADE-3 Phase 3 clinical trial evaluating fasedienol for the acute treatment of social anxiety disorder. The open label extension of the study is currently ongoing.

"The completion of the PALISADE-3 Phase 3 public speaking challenge study marks an important milestone for Vistagen," said Shawn Singh, President and Chief Executive Officer. "As we advance toward our expected topline results later this quarter, we remain encouraged by fasedienol's potential to become the first and only acute treatment for the more than 30 million people living with social anxiety disorder. We are grateful to the individuals who participated in this study, as well as the clinical investigators, site staff, and our contract research organization for their commitment and collaboration."

In August 2023, Vistagen reported positive results from its randomized, double-blind, placebo-controlled PALISADE-2 Phase 3 trial of fasedienol for the acute treatment of social anxiety disorder. The PALISADE-3 trial, and concurrent PALISADE-4 Phase 3 trial, involve the same public speaking challenge study design and primary efficacy endpoint as PALISADE-2, with certain protocol and operational enhancements related to site training, surveillance, and subject selection. The topline results for PALISADE-4 are anticipated in the first half of 2026.

Both PALISADE-3 and PALISADE-4 are designed to evaluate the efficacy and safety of a single dose of fasedienol in reducing anxiety symptoms during a simulated public speaking challenge in a clinical setting, using the Subjective Units of Distress Scale as the primary endpoint. PALISADE-3 subjects who choose to continue with the open label extension of the study can use fasedienol for up to twelve months in their daily lives. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of fasedienol for the acute treatment of social anxiety disorder. Vistagen believes that either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, could provide substantial evidence of fasedienol's effectiveness to support a potential New Drug Application (NDA) submission to the FDA for the acute treatment of social anxiety disorder.

About Social Anxiety Disorder

Social anxiety disorder 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, social anxiety disorder persists for many years thereafter, with a reported mean duration of about 20 years. While often a long-term disorder, social anxiety disorder can manifest acutely when triggered by anxiety-provoking social and performance situations during which individuals with social anxiety disorder 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 occupational functioning. Anxiety associated with social anxiety disorder often results in avoidance of everyday interactions and opportunities in academic, social, and vocational settings and an increased risk of serious co-morbid depression and substance use disorders, and potentially life-threatening, suicidal ideation, and suicide.

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 new class of intranasal product candidates called pherines. Pherines specifically and selectively bind as agonists on peripheral receptors on human nasal chemosensory neurons and are designed to rapidly trigger 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 if successfully developed and approved.

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, vasomotor symptoms (hot flashes) associated with menopause and premenstrual dysphoric disorder. Connect at www.Vistagen.com.

Forward-looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws, including, without limitation, statements regarding the expected timing of topline results for the PALISADE-3 and PALISADE-4 clinical trials, fasedienol's potential to become the first and only acute treatment for social anxiety disorder, and the potential for any of Vistagen's PALISADE Phase 3 clinical trials to support a NDA submission to the FDA for fasedienol for the acute treatment of social anxiety disorder. 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 those that are a part of Vistagen's PALISADE Phase 3 program, as currently expected or at all; submission of a NDA to the FDA for any of Vistagen's product candidates, including fasedienol; the ability of any clinical trial information submitted by Vistagen to the 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; 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, 2025, and Quarterly Report on Form 10-Q for the period ended June 30, 2025, 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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