Vistagen Achieves Minimum ICH Safety Exposure Recommendations Across Clinical Program for Fasedienol for the Acute Treatment of Social Anxiety Disorder

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 9, 2026-- 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 Company's clinical program for fasedienol nasal spray for the acute treatment of social anxiety disorder has achieved the minimum patient exposures as recommended under ICH E1, the international regulatory standard governing safety database exposure recommendations for drugs intended for long-term treatment (chronic or repeated intermittent use for longer than 6 months) of non-life-threatening conditions[1].

As of May 31, 2026, the Company estimates that the fasedienol clinical development program now exceeds ICH E1 minimum recommendations with over 1,500 subjects receiving at least a single exposure to fasedienol, over 300 subjects with at least 6-months of exposure, and over 100 subjects with at least 12 months of exposure. The 6-month and 12-month exposure numbers represent Vistagen's estimate of the number of subjects who have completed the 6-month and 12-month visits in the fasedienol open-label safety studies. These exposure estimates are expected to continue to increase to the extent they include subjects currently participating in the ongoing open label extension portion of Vistagen's PALISADE-3 and PALISADE-4 Phase 3 studies, as well as the randomized and open label portions of its Phase 2 repeat dose study. Although the Company believes the minimum ICH E1 recommendations have been met, Vistagen has not yet aligned with the FDA on the specific patient exposure requirements to support a potential fasedienol NDA submission.

"Achieving ICH E1 minimum safety exposure recommendations for fasedienol marks another important milestone in our social anxiety disorder program, and it has been encouraging to see subjects continue to opt into the open label extension portions of our PALISADE-3, PALISADE-4, and repeat dose studies," said Shawn Singh, President and Chief Executive Officer. "We are encouraged to reach this level of exposure, with fasedienol having been well-tolerated across our completed clinical trials to date."

Topline results from the randomized, double-blind, placebo-controlled portion of PALISADE-4, Vistagen's Phase 3 clinical trial evaluating fasedienol nasal spray for the acute treatment of social anxiety disorder, are expected in the second quarter of 2026. Topline results from the Phase 2 Repeat Dose study are expected in the third quarter of 2026. Vistagen believes that PALISADE-4, if successful, together with the positive results from its PALISADE-2 Phase 3 trial and further evidence Vistagen plans to generate to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol, could provide substantial evidence of fasedienol's effectiveness in support of a potential fasedienol U.S. 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. While often experienced on a long-term basis, social anxiety disorder can manifest acutely when triggered by anxiety-provoking social and performance situations in daily life, causing anxiety, distress, and the fear of embarrassment, judgment, and humiliation. Social anxiety disorder can also significantly disrupt social life and hinder occupational functioning, as well as increase the risk of depression and substance use disorders, suicidal ideation, and suicide.

About Fasedienol Nasal Spray for Acute Treatment of Social Anxiety Disorder

Fasedienol, Vistagen's most advanced neurocircuitry-focused investigational pherine product candidate, is in U.S. Phase 3 clinical development for the acute treatment of anxiety in adults with social anxiety disorder. Fasedienol's proposed mechanism of action (MOA) is fundamentally differentiated from all FDA-approved anti-anxiety medications. When administered intranasally in microgram-level doses, neurocircuitry-focused fasedienol modulates the nasal-limbic amygdala fear and anxiety neurocircuits involved in the pathophysiology of social anxiety disorder. Fasedienol is pharmacologically active without requiring apparent systemic absorption or uptake into the brain to achieve its rapid-onset anxiolytic effects. Fasedienol also has no observed binding on certain cellular receptors isolated from the brain that are associated with known drug abuse liability potential (for example, dopamine and opiate receptors) when activated by certain other pharmaceutical compounds for psychiatric disorders. Unlike benzodiazepines, fasedienol has no observed potentiation of GABA-A receptors. Because of its innovative non-systemic neurocircuitry-focused proposed MOA, Vistagen believes fasedienol has the potential to achieve rapid-onset anxiolytic effects for individuals with social anxiety disorder on an acute, as-needed basis, with a significantly reduced risk of unwanted side effects and safety concerns, such as potential drug-drug interactions, abuse, misuse, and addiction, associated with certain current oral and other systemically absorbed neuropsychiatric pharmaceuticals that act directly on neurons in the brain and are sometimes prescribed off-label for the acute treatment of social anxiety disorder. The FDA has granted Fast Track designation for the development of fasedienol for the acute treatment of social anxiety disorder.

About Vistagen

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 rapid-onset neurocircuitry-focused intranasal product candidates called pherines. Vistagen's pherine product candidates 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's most advanced intranasal pherine product candidates are fasedienol in U.S. Phase 3 development for the acute treatment of social anxiety disorder, itruvone for treatment of major depressive disorder, and refisolone for treatment of vasomotor symptoms (hot flashes) due to 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, including, without limitation, statements regarding Vistagen's beliefs about the significance of achieving minimum patient exposure recommendations referenced in the ICH E1 guidance; the favorable safety and tolerability data of fasedienol observed to date; the potential implications of data collected from Vistagen's PALISADE Phase 3 clinical development program for fasedienol; the expected timing of topline results from the randomized portion of PALISADE-4 and the Repeat Dose Study; Vistagen's plans to generate additional evidence to support the clinical meaningfulness of the duration and magnitude of effect of fasedienol; and Vistagen's belief that successful results from its PALISADE Phase 3 development program, including PALISADE-4, could provide substantial evidence of fasedienol's effectiveness in support of a potential U.S. NDA submission to the FDA. 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. In addition, achievement of patient exposure levels referenced in ICH E1 does not establish that the FDA will determine Vistagen's safety database is sufficient to support a potential U.S. NDA submission or regulatory approval. 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 fasedienol PALISADE Phase 3 program, as currently expected or at all; Vistagen's ability to ability to successfully employ cash preservation measures and/or secure adequate financing for its operations, including financing or collaborative support for continued clinical development of its product candidates; 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; the scope and enforceability of Vistagen's patents, including patents related to Vistagen's pherine product candidates; and other technical and unexpected hurdles in the development, manufacture and/or potential commercialization of Vistagen's product candidates. These risks and others are more fully discussed in the section entitled "Risk Factors" in Vistagen's Quarterly Report on Form 10-Q for the period ended December 31, 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.

References:

1. ICH E1: Extent of Population Exposure to Assess Clinical Safety Scientific Guideline, 1994

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