Vistagen Presents New Research on the Impact of Social Anxiety Disorder at The Anxiety and Depression Association 2025 Conference

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New Data Build on Recent Epidemiology Findings Presented by the Company at the 2024 Neuroscience Education Institute Congress

The Need for Improved Diagnosis and Treatment Options Underscored by Data Presented in Posters

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 17, 2025-- Vistagen (Nasdaq: VTGN), a clinical-stage biopharmaceutical company pioneering neuroscience with nose-to-brain neurocircuitry to develop and commercialize a new class of intranasal product candidates called pherines, presented new data on social anxiety disorder (SAD) at the 2025 Anxiety and Depression Association of America (ADAA) Conference in Las Vegas, Nevada. The Company's poster presentations examined the age of onset of SAD in participants in the Company's fasedienol PALISADE Phase 3 program studies completed to date, as well as new data on the epidemiology of young adults with and without SAD from the National Health and Wellness survey (NHWS). The new research builds on epidemiology data on SAD prevalence and demographics presented by Vistagen at the 2024 Neuroscience Education Institute (NEI) Congress using the 2023 NHWS with over 75,000 respondents in the U.S.

"This new research provides a clearer and more comprehensive picture of social anxiety disorder — shining light on its rising prevalence and significant impact on young adults," said Ross Baker, Ph.D., MBA, Vice President, Medical Strategy at Vistagen and a co-author of the research. "Existing therapies remain limited, and these findings reinforce the urgent need for new treatment options. The new research also highlights the critical role of timely diagnosis to improve patient outcomes."

The key findings from the poster presentations by Vistagen at the ADAA and NEI conferences reveal important insights into SAD, including:

Overall prevalence:

- SAD affects nearly 31 million adults in the U.S.
- The prevalence of SAD overall among adults in the U.S. has increased over time, with the largest increase being among adults in the youngest age group (18–22 years).
- Although the rate of U.S. adults who experienced SAD has increased over time, the rate of SAD diagnosis has not increased, and treatment rates have decreased.
- More than one in five U.S. adults surveyed who experienced SAD reported suicidal ideation on more than half the days in the past two weeks and worse mental health quality of life than the general U.S. adult population.
- Over three-quarters of those experiencing SAD reported mild to severe depression.

Subgroup aged 18-22:

- The prevalence of SAD experienced among U.S. young adults has increased over time, while the proportion of those treated for SAD has decreased.
- Close to half (48.1%) of U.S. young adults surveyed who reported experiencing SAD also reported suicidal ideation on at least several days in the past 2 weeks, markedly higher than those without SAD (31.6%).
- Those with SAD also had higher rates of depression and worse mental health quality of life than those without SAD.
- Among those experiencing SAD, economic factors were generally worse than those not experiencing SAD: lower rates of full-time employment; significantly higher rates of household incomes lower than $50,000; and significantly greater impairment in productivity and activity.
- These findings collectively elucidate the importance of diagnosing/treating SAD and providing social support, as well as various alternative mechanisms to cope with SAD.

Age of onset of SAD in participants in Vistagen's fasedienol Phase 3 studies completed to date :

- Approximately 30% of participants in Vistagen's PALISADE Phase 3 Program studies of fasedienol nasal spray completed to date had a self-reported early onset of SAD in childhood, at 10 years of age or younger.
- Remarkably, the time to first treatment for SAD was, on average, 27 years from time of onset for the early-onset group and, on average, 18 years from onset for the adolescent/adult-onset group, underscoring a high unmet need for diagnosis and treatment of SAD, especially among children and adolescents.
- Baseline severity of SAD and psychiatric and treatment histories were similar between early onset and adolescent/adult-onset subjects.
- History of alcohol/drug use was higher in the early-onset group than the adolescent/adult-onset group.

Key Takeaways from this Research:

- Promoting timely diagnosis and treatment of SAD is needed to improve various patient-reported outcomes, including physical and mental health and work productivity.
- Approved treatments for SAD are limited, and new treatments are needed.
- In conjunction with treatments, providing young adults with social support and various alternative mechanisms to cope with SAD is imperative.
- Consumer education on the severity of SAD may also help drive discussions with healthcare providers.

The posters presented by Vistagen at the ADAA and NEI conferences are available on the Publications page of the Company's website.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a 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 in human nasal chemosensory neurons, rapidly activating olfactory bulb-to-brain neurocircuits which regulate brain areas involved in behavior and autonomic nervous system activity. They achieve therapeutic benefits without requiring absorption into blood, or uptake into the brain, giving them a differentiated safety profile vs. 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 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. Among other things, there can be no guarantee that fasedienol or any of Vistagen's other product candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. These risks and others 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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