Vistagen Presents Poster at Psych Congress 2022 Highlighting Effect of PH94B on Nasal Electrogram Responses and Biomarkers of Autonomic Nervous System Activity in Healthy Human Subjects

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In healthy subjects, intranasal administration of PH94B activated nasal chemosensory cells, rapidly reduced sympathetic tone, and provided rapid self-reported calmness

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 19, 2022-- Vistagen (Nasdaq: VTGN), a clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other central nervous system (CNS) disorders, today announced that data highlighting intranasal administration of PH94B, the Company's first-in-class synthetic investigational pherine nasal spray in Phase 3 development for acute treatment of social anxiety disorder, were presented at Psych Congress in New Orleans on September 18, 2022.

PH94B is an investigational pherine nasal spray thought to regulate the olfactory-amygdala circuits of fear and anxiety without direct GABA-A receptor activation or binding to other CNS receptors. In the presented study, Vistagen compared the effect of intranasal administration of PH94B and steroidal hormones on the electrical activity (the electrogram) of the nasal chemosensory mucosa and on biomarkers of autonomic nervous system activity.

Data presented suggest that intranasal administration of PH94B to healthy volunteers significantly increased the electrogram response recorded from the nasal mucosa, while rapidly lowering heart rate, respiratory rate, and electrodermal activity consistent with decreased sympathetic nervous system activity (which is activated in situations involving fear and stress, among others). After receiving intranasal PH94B, subjects felt calmer and less tense per self-report, suggesting an anxiolytic effect, while steroid hormones or placebo had no such effect on the measured biological or behavioral parameters. As with all clinical trials of PH94B completed to date, no severe or serious adverse events were reported for PH94B. These results support the Company's experimental program to demonstrate therapeutic biological and behavioral changes after intranasal administration of PH94B.

"Pherines are a new class of pharmaceuticals acting on receptors of nasal chemosensory cells that activate nasal-amygdala neural circuits controlling fear, anxiety, and mood, with rapid-onset of effect and without the need of systemic distribution or transport into the brain," stated Louis Monti, M.D., Ph.D., Vistagen's Vice President, Translational Medicine. "These positive data support the activation of target nasal receptors and sympatholytic effects following intranasal administration of PH94B, concurrent with self-reported calmness and relaxation, further contributing to our understanding PH94B's proposed mechanism of action and its potential to produce fast-acting anxiolytic effects."

About PH94B

Vistagen's PH94B is a first-in-class, rapid-onset (approximately 15 minutes) investigational pherine nasal spray with a novel proposed mechanism of action (MOA) that regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system, without systemic distribution, potentiation of GABA-A or direct activity on CNS neurons in the brain. Vistagen is evaluating PH94B in Phase 3 development for the acute treatment of anxiety in adults with social anxiety disorder and in exploratory Phase 2 development for the treatment of adjustment disorder with anxiety. Designed for intranasal administration in low microgram doses, the proposed novel MOA of PH94B is fundamentally differentiated from all currently approved anti-anxiety medications, including benzodiazepines.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. PH94B and PH10 belong to a new class of drugs known as pherines, which are investigational neuroactive steroid nasal sprays designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic distribution or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. 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 any pharmaceutical product, 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 the Company's PALISADE-2 Phase 3 clinical trial will be successful or that PH94B or any of the Company's other drug candidates will receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to resuming and completing the Company's PALISADE-2 Phase 3 clinical trial; the effect, if any, of the previously announced topline results of the Company's PALISADE-1 Phase 3 clinical trial; the completion and results of the Company's ongoing clinical studies of PH94B, including the Company's Phase 2A clinical trial of PH94B in adults experiencing adjustment disorder with anxiety; delays in launching, conducting and/or completing other ongoing and planned clinical trials,

including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct the Company'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 the Company's CNS drug candidates. These risks are fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2022 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the U.S. Securities and Exchange Commission (SEC). The Company'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 the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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