



Vistagen Presents New Fasedienol (PH94B) Research at 2023 Anxiety and Depression Association of America Conference

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Results from new study further support that fasedienol acts locally in the nasal passages and does not require systemic uptake or direct activity on neurons in the brain to achieve fast-acting anti-anxiety effects

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 19, 2023-- [Vistagen](#) (Nasdaq: VTGN), a late 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 new data, presented at the 2023 Anxiety and Depression Association of America (ADAA) Conference in Washington, D.C., that further supporting the proposed mechanism of action (MOA) of fasedienol (PH94B), the Company's rapid-onset investigational pherine nasal spray in Phase 3 development for the treatment of social anxiety disorder (SAD). Findings from the study demonstrate local metabolism and clearance of fasedienol from the nasal passages. This discovery of the local nasal clearance of fasedienol may explain prior research findings that fasedienol is absent from systemic circulation and from the brain after intranasal administration, contributing to its favorable safety profile in all clinical studies to date, which studies have involved over 30,000 doses of fasedienol administered to adults with SAD.

In the study, cells were extracted from the epithelial lining of the dorsal nasal septum of each nasal passage in healthy adult volunteers. Results from incubation of fasedienol with human nasal epithelial cells show that it is progressively metabolized and cleared from the nasal passages by P450-CYP enzymes expressed in nasal epithelial cells, including chemosensory cells, after intranasal spray administration.

"The results of this study provide further evidence to support our belief that fasedienol activates nasal-amygdala neural circuits acting locally on nasal receptors and does not require systemic uptake or direct activity on neurons in the brain to achieve rapid-onset anti-anxiety effects," said Dr. Louis Monti, Vice President of Translational Medicine at Vistagen. "The absence of systemic uptake of fasedienol and other fast-acting pherines is essential in our efforts to develop new drug candidates for anxiety, depression and other CNS disorders without most of the potential side effects and safety concerns associated with current oral therapies, all of which require systemic uptake."

About Fasedienol (PH94B)

Vistagen's fasedienol (PH94B) is a first-in-class, rapid-onset 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 receptors or direct activity on neurons in the brain. Vistagen is developing fasedienol in a Phase 3 program for the treatment of social anxiety disorder. Designed for intranasal administration in low microgram doses, the proposed novel MOA of fasedienol is fundamentally differentiated from all currently approved anti-anxiety medications, including all antidepressants and benzodiazepines.

About Social Anxiety Disorder

Social anxiety disorder (SAD) affects an estimated 25 million Americans. A person with SAD feels intense, persistent symptoms of anxiety or fear in certain social situations, such as meeting new people, making comments in a business meeting, dating, being on a job interview, answering a question in class, or talking to a cashier in a store. Doing common, everyday things in front of people causes profound anxiety or fear of being embarrassed, evaluated, humiliated, judged, or rejected. SAD can get in the way of going to work, attending school, or doing a wide variety of things in a situation that is likely to involve interpersonal interaction. It can lead to avoidance and opportunity costs that can significantly impact a person's employment and social activities and can be very disruptive to their overall quality of life. SAD is commonly treated long-term with certain FDA-approved antidepressants, which have a slow onset of effect (several weeks) and provide limited therapeutic benefits, and with benzodiazepines, which are not FDA-approved for treating SAD. Both antidepressants and benzodiazepines have known side effects and significant safety concerns that may make them unattractive to individuals affected by SAD.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. Vistagen is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available for treatment of anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes six product candidates, including fasedienol (PH94B), itruvone (PH10) and three additional investigational agents belonging to a new class of drugs known as pherines, in addition to AV-101, which is an oral antagonist of the N-methyl-D-aspartate receptor (NMDAR). Pherines, which are administered as nasal sprays, are designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can beneficially impact key neural circuits in the brain without systemic uptake 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, depression and several other CNS disorders. 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 development may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's ability to secure adequate financing for its operations, including financing or collaborative support for continued clinical development of fasedienol (PH94B) and/or its other product candidates; the completion and results of the Company's ongoing clinical studies of itruvone (PH10) and AV-101; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; the scope and enforceability of the Company's patents; fluctuating costs of materials and other resources and services 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 more 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 December 31, 2022, 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). The Company's SEC filings are available on the SEC's website at www.sec.gov. Additionally, you should not place undue reliance on these forward-looking statements in the future, because they 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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