Vistagen Presents Fasedienol (PH94B) Safety and Exploratory Efficacy Data from Phase 3 Open-Label Social Anxiety Disorder Study at American Society for Clinical Psychopharmacology Annual Meeting

June 1, 2023

Favorable long-term, open-label treatment data from nearly 500 patients in real-world setting suggest that patient-tailored, as-needed administrations of fasedienol over time were safe and well-tolerated

Positive exploratory fasedienol efficacy data measured by the Liebowitz Social Anxiety Scale (LSAS) demonstrated clinically meaningful reductions in fear, anxiety and avoidance of anxiety-provoking social and performance situations in daily life, building on LSAS data from a previous real-world, placebo-controlled Phase 2 study of fasedienol in social anxiety disorder

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 1, 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 that positive safety and exploratory efficacy data from its large Phase 3 open-label study of fasedienol (PH94B) nasal spray for the treatment of anxiety in adults with social anxiety disorder (SAD) were presented in a late-breaking poster presentation at the American Society for Clinical Psychopharmacology (ASCP) 2023 Annual Meeting taking place in Miami from May 30 through June 2, 2023.

The study was conducted in a real-world setting and was designed to evaluate the long-term safety and tolerability of multiple, patient-tailored, as-needed administrations of fasedienol in adults with SAD when they experienced social and performance stressors in their daily lives.

Safety

Long-term administration of 3.2 µg of fasedienol, as-needed up to four times per day, was safe and well-tolerated, with no new safety findings or trends identified, regardless of the number of doses administered by each subject (safety population: n=481), as previously reported. Headache was the most common treatment-emergent adverse event (TEAE) (17.0%); no other TEAE occurred in more than 5.0% of subjects, except for COVID-19 TEAEs (11.4%), which were not considered related to fasedienol. Over 30,000 doses of fasedienol were administered by patients during the study.

Exploratory Efficacy

The study also evaluated the change from baseline in monthly standard clinical measurements and behavioral assessment scales (the LSAS, Clinician Global Impression of Improvement scale (CGI-I) and Patient Global Impression of Change scale (PGI-C)) in response to anxiety-provoking social and performance situations in patients' daily lives after the administration of fasedienol.

LSAS Improvement

The key exploratory endpoint in the study included evaluation of the change from baseline on the LSAS, which measures SAD patients' response to anxiety-provoking social and performance situations experienced in their daily lives. The LSAS was the primary efficacy endpoint in all registration studies for the three FDA-approved treatments for adults with SAD.

As presented in the poster, analysis of the final data set from the study demonstrates clinically meaningful functional improvement, as measured by the LSAS, and total LSAS scores, in both men and women, continued to decline in consecutive months during the study, as follows:

- After 1 month, the mean reduction on the LSAS was 16 points (n=385);
- After 2 months, the mean reduction on the LSAS was 20 points (n=324); and
- After 3 months, the mean reduction on the LSAS was 24 points (n=218).

For subjects who continued in the study, total LSAS scores continued to decline from baseline, with improvements observed each month on the LSAS through nine months. The continued improvement in LSAS scores is indicative of the therapeutic potential of multiple, patient-tailored, as-needed administrations over time as fasedienol helps patients build confidence to engage in anxiety-provoking social and performance situations in their daily lives more frequently and with less fear and anxiety.

Clinician-rated Improvement

The CGI-I results indicated 43% of the 218 patients assessed after three months were "much" or "very much" improved.

Patient-rated Improvement

The PGI-C results indicated 44% of the 218 patients assessed after three months considered themselves "much" or "very much" improved.

"These data advance the body of evidence supporting fasedienol's safety profile and potential to achieve overall reduction in anxiety for adults suffering with social anxiety disorder, and we were excited to present these important findings to the ASCP community. There are significant gaps in care for mental health patients, and many are seeking fast-acting medications with a favorable safety profile," said Shawn Singh, Chief Executive Officer of Vistagen. "When used as-needed and over time in their daily lives, as in this open-label study and a prior placebo-controlled Phase 2 study, we believe fasedienol, with its exceptional safety profile has the potential to help change the treatment landscape for social anxiety disorder."

The abstract of the poster is currently available at the ASCP Annual Meeting website and the full poster will be available at https://www.vistagen.com/publication after the conclusion of the conference on June 2, 2023.

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 clinical-stage product candidates, including five investigational agents belonging to a new class of drugs known as pherines, in addition to AV-101, an oral antagonist of the glycine site of the N-methyl-D-aspartate receptor (NMDAR). Pherines, which are administered as nasal sprays, are designed with an innovative rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can selectively and beneficially impact key neural circuits in the brain without requiring systemic uptake or direct activity on CNS neurons. Vistagen's AV-101 inhibits activity of the ion channel of the NMDAR but does not block it. 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 other product candidates; the completion and results of the Company's ongoing and/or future 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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