Vistagen to Present Positive Fasedienol Phase 3 Data and Positive PH80 Phase 2A Data at Upcoming Scientific Conferences

November 7, 2023

Positive top-line results from fasedienol (PH94B) Phase 3 PALISADE-2 trial in social anxiety disorder (SAD) to be presented by SAD expert, Dr. Michael Liebowitz, at CNS Summit 2023

Positive results from PH80 Phase 2A study in women diagnosed with vasomotor symptoms (hot flashes) due to menopause to be presented at the 2023 Neuroscience Education Institute (NEI) Congress

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 7, 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 the Company will present at two upcoming scientific conferences in November.

“Vistagen’s presentations highlight the significant progress we have made to advance new therapies to address urgent unmet patient needs,” said Shawn Singh, Chief Executive Officer of Vistagen. “We look forward to initiating our PALISADE-3 Phase 3 clinical trial in social anxiety disorder early next year.”

Key highlights of the oral and poster presentations include:

- Fasedienol data demonstrating statistically significant rapid-onset reduction in patient-reported Subjective Units of Distress Scale (SUDS) score compared to placebo in a public speaking challenge (primary endpoint, p=0.015) in adults diagnosed with social anxiety disorder (SAD).
- Fasedienol data demonstrating long-term, open-label treatment from nearly 500 patients was safe and well-tolerated and provided improved overall symptom control in adults with SAD.
- PH80 data demonstrating statistically significant reduction in the number of hot flashes compared to placebo (p<.001) after four weeks of treatment in women diagnosed with vasomotor symptoms (hot flashes) due to menopause.

CNS Summit 2023

Podium Presentation
Date: Friday, November 10, 2023
Time: 12:00 p.m. to 3:00 p.m. Eastern Time
Session: Neuroscience Spotlight
Topic: Top-Line Results from Phase 3 PALISADE-2 Trial of Fasedienol (PH94B) Nasal Spray for the Acute Treatment of Social Anxiety Disorder
Presenter: Michael Liebowitz, MD

2023 Neuroscience Education Institute (NEI) Congress

Poster Presentation
Date: Friday, November 10, 2023
Title: Top-Line Results from Phase 3 PALISADE-2 Trial of Fasedienol (PH94B) Nasal Spray in Social Anxiety Disorder
Authors: Michael R. Liebowitz, MD; Ester Salmán, MPH; Rita Hanover, PhD; Brittany Reed, PA; Ross A. Baker, PhD; Louis Monti, MD, PhD
Presenter: Louis Monti, MD, PhD
Poster Number: 109

Poster Presentation
Date: Friday, November 10, 2023
Title: A Phase 2A Clinical Study to Investigate the Efficacy, Safety, and Tolerability of PH80 for the Acute Management of Menopausal Vasomotor Symptoms (Hot Flashes) in Women
Authors: Louis Monti, MD, PhD; Ross A. Baker, PhD; Ester Salman, MS; Rita Hanover, PhD
Presenter: Ross A. Baker PhD
Poster Number: 47

Poster Presentation

Date: Friday, November 10, 2023
Title: A Phase 3 Open-label Safety Trial of Fasedienol (PH94B) Nasal Spray in the Treatment of Anxiety in Adults with Social Anxiety Disorder (SAD)
Authors: Jaakko Lappalainen, MD, PhD; Ester Salmán, MPH; Rita Hanover, PhD; Brittany Reed, PA; Ross A. Baker, PhD; Mark A. Smith, MD, PhD; Michael R. Liebowitz, MD
Presenter: Brittany Reed, PA
Poster Number: 89

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 currently available for the treatment of anxiety, depression, and multiple CNS disorders. Vistagen's pipeline contains six clinical-stage product candidates, including fasedienol (PH94B), itruvone (PH10), PH80, PH15, and PH284, each an investigational agent belonging to a new class of drugs known as pherines, as well as AV-101, which is an oral prodrug of an antagonist of the N-methyl-D-aspartate receptor (NMDAR). Pherines are neuroactive nasal sprays designed with an innovative and differentiated proposed mechanism of action (MOA) that activates chemosensory neurons in the nasal cavity and can beneficially impact key neural circuits in the brain without systemic absorption or direct activity on 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 the Company and its management, are inherently uncertain. These risks and uncertainties are fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended March 31, 2023, and in our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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). Our SEC filings are available on the SEC’s website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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Investors:
Mark McPartland
Senior Vice President, Investor Relations
(650) 577-3606
markmcp@vistagen.com

Media:
Nate Hitchings
SKDK
nhitchings@skdknick.com

Source: Vistagen