



VistaGen Announces Publication in CNS Spectrums Detailing Proposed Mechanism of Action of Its Investigational Neuroactive Nasal Sprays for Anxiety and Depression Disorders

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Dr. Louis Monti, VistaGen's Newly-Appointed Vice President, Translational Medicine, and Dr. Michael Liebowitz, VistaGen CNS Clinical and Regulatory Advisory Board Member, Collaborate on Review

SOUTH SAN FRANCISCO, Calif., Dec. 30, 2020 (GLOBE NEWSWIRE) -- [VistaGen Therapeutics](#), Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, announced today that Dr. Louis Monti, VistaGen Vice President, Translational Medicine, and Dr. Michael Liebowitz, VistaGen CNS Clinical and Regulatory Advisory Board Member, authored an article published in [CNS Spectrums, a Cambridge University Press journal](#), on the proposed mechanism of action of the Company's investigational neuroactive nasal sprays, PH94B and PH10, currently in development as potential rapid-onset treatments for anxiety and depression disorders, respectively.¹ The publication details the proposed neural circuits mediating the mechanism of action of *pherines*, including PH94B and PH10, which are synthetic neuroactive steroids designed to engage nasal chemosensory receptors and produce rapid-onset anxiolytic and antidepressant effects, respectively.

PH94B and PH10, which are administered in microgram-level doses, are designed to achieve therapeutic benefits without requiring systemic uptake, potentially avoiding the side effects and safety concerns often associated with current antidepressants and anxiolytics, including benzodiazepines.

"PH94B and PH10 were discovered and developed for their specific therapeutic potential to treat anxiety and depression disorders, representing a new class of neuropharmaceuticals," said Dr. Monti. "When current anxiolytics and antidepressant drugs are administered systemically, milligram-level doses of the drugs are often needed to achieve the desired therapeutic effects. In contrast, with the innovative pharmacology of PH94B and PH10, we believe only microgram-level doses administered intranasally onto the receptors in the nasal passage are required to achieve the desired neural activity."

"Bringing hope to individuals who continue to suffer from anxiety and depression is at the core of VistaGen's mission," added Shawn Singh, VistaGen's Chief Executive Officer. "This publication, authored by Drs. Monti and Liebowitz, demonstrates the exciting potential of *pherines*, including both PH94B and PH10, to become paradigm-shifting treatments in our efforts to improve global mental health, an unmet need that is perhaps more apparent now than ever before as a result of the devastating COVID-19 pandemic. We have an exciting opportunity to make a difference, and we look forward to keeping our stakeholders informed of our progress on that goal."

Before his appointment at VistaGen, Dr. Monti served in multiple leadership roles at Pherin Pharmaceuticals, including President and CEO, Executive Vice President and Vice President of Research.

Dr. Liebowitz is a professor of clinical psychiatry at Columbia University and the former Director and Founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute. He retired in 2006 as the Director of the Anxiety Disorders Clinic, a position that he held since 1982, and is a member of the American Society of Clinical Psychopharmacology, Anxiety Disorder Association of America Scientific Advisory Board, American College of Neuropsychopharmacology and American Psychiatric Association.

1. [Monti, L., & Liebowitz, M. \(2020\). Neural circuits of anxiolytic and antidepressant pherine molecules. *CNS Spectrums*, 1-7. doi:10.1017/S109285292000190X](#)

About PH94B

PH94B is an innovative odorless investigational synthetic neuroactive steroid nasal spray with therapeutic potential in multiple mental health disorders involving anxiety or phobia and is designed to have a rapid-onset. During Phase 2 clinical studies for the potential treatment of social anxiety disorder (SAD), PH94B was self-administered in microgram-level doses and produced rapid-onset (within approximately 15 minutes) anti-anxiety effects without sedation or systemic uptake and distribution.

VistaGen is currently preparing PH94B for Phase 3 development as a potential acute treatment of anxiety in adults with SAD. The FDA has granted Fast Track designation for the development of PH94B for this indication.

With rapid-onset pharmacology and favorable safety results seen in all clinical studies to date, VistaGen believes PH94B has the potential to provide an innovative treatment alternative to benzodiazepines and other pharmaceuticals in the acute treatment paradigm for SAD and other anxiety disorders.

About PH10

PH10 is an innovative odorless investigational synthetic neuroactive steroid nasal spray designed to have rapid-onset therapeutic potential in several neuropsychiatric indications involving depression, including major depressive disorder (MDD) and suicidal ideation. Following successfully completed exploratory Phase 2A clinical development, VistaGen is preparing for Phase 2B clinical development of PH10 as a potential stand-alone, rapid-onset treatment for MDD.

About VistaGen

VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go

beyond the current standard of care for anxiety, depression, and other CNS disorders. Each of VistaGen's three drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

Forward Looking Statements

Various statements in this release are "forward-looking statements" concerning our future expectations, plans and prospects, including the proposed mechanism of action of pherines, PH94B and PH10 and potential for successful clinical development and commercialization of PH94B for anxiety disorders and PH10 for depression disorders. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: the mechanism of action of pherines, PH94B and PH10 is not as proposed; development and approval of PH94B and PH10 may not be achieved in any market; the FDA may decide that the results of our PH94B and PH10 clinical programs are not sufficient for regulatory approval for acute treatment of anxiety in adult patients with SAD or MDD, respectively, or any other anxiety- or depression-related disorder; development of PH94B and PH10 may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed in future studies, which may not support further development or be sufficient to gain regulatory approval to market PH94B or PH10; adverse events may be encountered at any stage of development that negatively impact further development. Other risks and uncertainties include, but are not limited to, issues related to: adverse healthcare reforms and changes of laws and regulations; general industry and market conditions; manufacturing and marketing risks, including risks associated with the COVID-19 pandemic, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B or PH10; inadequate and/or untimely supply of PH94B or PH10 to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B and PH10, as well as those risks more fully discussed in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended March 31, 2020, and in our most recent Quarterly Report on Form 10-Q for the quarter and six months ended September 30, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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