



## Positive Pilot Phase 3 Data Position VistaGen's PH94B Neuroactive Nasal Spray for Pivotal Phase 3 Development as a Novel, As-Needed Treatment for Social Anxiety Disorder

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***PH94B has potential to be the First FDA-Approved PRN Treatment for Social Anxiety Disorder***

***New Findings Presented at the 2019 Anxiety and Depression Association of America Annual Conference***

**SOUTH SAN FRANCISCO, CA / ACCESSWIRE / April 1, 2019 / [VistaGen Therapeutics](#)** (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression, social anxiety disorder and other central nervous system (CNS) diseases and disorders with high unmet need, announced today additional results from a positive pilot Phase 3 study of PH94B, a potential first-in-class neuroactive nasal spray shown to be effective on an as-needed (PRN) basis for treatment of social anxiety disorder (SAD). The new data were presented in a poster session at the [2019 Anxiety and Depression Association of America \(ADAA\) Annual Conference](#) in Chicago.

In the 22-patient, four-week, randomized, double blind, placebo-controlled pilot Phase 3 crossover study, subjects receiving PH94B had a significantly greater decrease in average peak Subjective Units of Distress scores compared to placebo within one week of treatment.<sup>1</sup> There was also a significantly greater decrease in Liebowitz Social Anxiety Scale (LSAS) avoidance scores for subjects who received PH94B first, before crossing over to placebo. Administered at microgram doses and consistent with results from prior Phase 2 studies, PH94B's safety profile was excellent, with no serious adverse events. VistaGen is currently preparing for pivotal Phase 3 development of PH94B as a novel first-line PRN treatment for SAD, with Dr. Michael Liebowitz, developer of the LSAS, a widely-used primary outcome measure in SAD for both clinical research and for evaluation in clinical practice, acting as Principal Investigator for the study.

"Social anxiety disorder is one of the most prevalent mental health conditions in the U.S., affecting as many as 15 million Americans. In both Phase 2 and pilot Phase 3 clinical studies, PH94B was more effective than placebo in the whole sample on the primary outcome measure. In the Phase 2 trial, which included both a public speaking and a social situation challenge, PH94B significantly improved the primary efficacy endpoint within 10 to 15 minutes of self-administration. These positive results demonstrate PH94B's potential to change the lives of millions of people suffering from SAD," said Dr. Liebowitz, Principal Investigator of the pilot Phase 3 study. "I support VistaGen's plans for a pivotal Phase 3 program launch in 2020. PH94B neuroactive nasal spray has potential to be the first FDA-approved PRN treatment for SAD."

"Current treatments for SAD fall far short of patient needs," stated Mark Smith, MD, PhD, VistaGen's Chief Medical Officer. "With its unique mechanism of action, exceptional safety profile and rapid-onset activity, we are excited about PH94B's potential to transform the current treatment paradigm for SAD. We look forward to working closely with the FDA and Dr. Liebowitz as we prepare for and execute pivotal Phase 3 development of PH94B for SAD."

### **About PH94B Neuroactive Nasal Spray**

PH94B neuroactive nasal spray is fundamentally different from all current treatments for SAD. Developed from proprietary compounds called pherines and administered as a nasal spray, PH94B activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety. Its novel mechanism of pharmacological action, rapid-onset of therapeutic effects and exceptional safety and tolerability profile shown in clinical trials to date make PH94B neuroactive nasal spray an excellent product candidate with potential to become the first FDA-approved PRN treatment for SAD.

In a published double-blind, placebo-controlled Phase 2 clinical trial, PH94B neuroactive nasal spray was significantly more effective than placebo in reducing public-speaking and social interaction anxiety on laboratory challenges of individuals with SAD.<sup>2</sup>

### **About Social Anxiety Disorder**

SAD affects as many as 15 million Americans and is the third most common psychiatric condition after depression and substance use. SAD is characterized by a persistent and unreasonable fear of one or more social or performance situations, where the individual fears that he or she will act in a way or show symptoms that will be embarrassing or humiliating, leading to avoidance of the situations when possible and anxiety or distress when they occur. These fears have a significant impact on the person's employment, social activities and overall quality of life. SAD is commonly treated chronically with antidepressants, which have a slow onset of effect (several weeks) and known side effects that may make them unattractive to individuals affected by SAD.

### **About VistaGen**

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for multiple CNS diseases and disorders with high unmet need. VistaGen's CNS pipeline includes three drug candidates (AV-101, PH10, and PH94B) with potential for at-home use, rapid-onset therapeutic benefits and exceptional safety. Each CNS drug candidate in VistaGen's pipeline is either currently in or has completed Phase 2 clinical development. AV-101, an oral NMDA receptor glycine site antagonist (a full antagonist), is in Phase 2 development in the U.S. for major depressive disorder (MDD) and in a first-step target engagement study in healthy volunteer U.S. military Veterans for suicidal ideation. The FDA has granted Fast Track designation for development of AV-101, both as a potential [adjunctive treatment for MDD](#) and as a [non-opioid treatment for neuropathic pain](#). PH10 is a potential first-in-class neuroactive nasal spray with rapid-onset antidepressant effects observed at microgram doses and

without systemic exposure. PH10 is in Phase 2 development for MDD. PH94B is a potential first-in-class neuroactive nasal spray with rapid-onset effects observed at microgram doses and without systemic exposure. Phase 2 and pilot Phase 3 development of PH94B for SAD has been completed successfully, and PH94B is now being prepared for pivotal Phase 3 development as an on-demand PRN treatment for SAD.

For more information, please visit [www.vistagen.com](http://www.vistagen.com) and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

1 [Liebowitz MR, Hanover R, Draine A, Lemming R, Careri J, Monti L \(2016\). Effect of as-needed use of intranasal PH94B on social and performance anxiety in individuals with social anxiety disorder. \*Depress Anxiety\* 33: 1081-1089.](#)

2 [Liebowitz MR, Salzman E, Nicolini H, Rosenthal N, Hanover R, Monti L \(2014\). Effect of an acute intranasal aerosol dose of PH94B on social and performance anxiety in women with social anxiety disorder. \*Am J Psychiatry\* 171:675-682.](#)

#### **Forward-Looking Statements**

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of our drug candidates, including AV-101 for MDD, neuropathic pain and suicidal ideation, PH94B for SAD, and PH10 for MDD, all of which constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients during our clinical development of any product candidate that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities, and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at [www.sec.gov](http://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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