VistaGen's Poster Presentation at the Anxiety and Depression Association of America's 2021 Annual Conference Differentiates PH94B's Mechanism of Action from Highly-Addictive Benzodiazepines

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SOUTH SAN FRANCISCO, Calif., March 22, 2021 (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 data highlighting the proposed mechanism of action (MOA) of its Phase 3 investigational drug candidate, PH94B nasal spray, were recently presented in a poster session at the Anxiety and Depression Association of America's 2021 Virtual Annual Conference. PH94B is designed with potential to provide rapid-onset acute treatment of anxiety for millions of individuals suffering from social anxiety disorder (SAD) without directly activating gamma-amino butyric acid (GABA-A) receptors. PH94B's MOA is, therefore, fundamentally differentiated from the MOA of benzodiazepines such as alprazolam, diazepam and lorazepam, which are direct GABA-A receptor positive modulators. Among VistaGen's core goals is for PH94B to displace these and other widely-used but highly-addictive benzodiazepines in the acute treatment paradigm for SAD and other anxiety disorders and phobias.

PH94B is an investigational odorless pherine nasal spray entering Phase 3 clinical development in the U.S. for the acute treatment of anxiety in adults with SAD, the third most common mental health disorder among Americans, affecting approximately 20 million individuals. PH94B also has therapeutic potential in a wide range of additional anxiety disorders and phobias. Self-administered in microgram-level doses, in Phase 2 clinical studies, PH94B produced rapid-onset anti-anxiety effects within approximately 15 minutes, without the troubling side effects associated with benzodiazepines.

To help differentiate PH94B's mechanism of action from that of benzodiazepines, VistaGen studied whether PH94B had positive modulatory effects on GABA receptors.

Key results in the recent ADAA poster presentation include the following:

- PH94B had no significant effect on GABA potentiation at doses up to 10 micromolar, compared to the 300 percent potentiation induced by diazepam, a commonly-prescribed benzodiazepine.
- The concentration of PH94B that gives the half-maximal response (EC_{50}) could not be calculated for PH94B, whereas diazepam's half-maximal response (EC_{50}) was 72 nanomolar.
- PH94B had no agonist or antagonist effects on GABA receptors compared to the effect of GABA (EC_{50}= 4.7 micromolar) and bicuculline (EC_{50}= 1.6 micromolar), respectively.

"The results are in agreement with PH94B's lack of benzodiazepine-like side effects and safety concerns reported in PH94B clinical studies – for example, lack of sedation, cognitive impairment or abuse liability potential," said Louis Monti, M.D., Ph.D., Vice President, Translational Medicine of VistaGen. "This study demonstrated that PH94B's mechanism of action is through neural regulation of forward inhibitory GABAergic neurons in the limbic amygdala and is differentiated from benzodiazepines' mechanism of action, which is through a direct local potentiating effect on GABA receptors. These data are key in understanding PH94B's overall potential effectiveness and safety for individuals suffering from SAD and many other anxiety disorders."

"Given the FDA's recent Drug Safety Communication that outlined and highlighted the safety risks associated with benzodiazepine use, the implications resulting from this study are significant," added Mark Smith, M.D., Ph.D., Chief Medical Officer of VistaGen. "PH94B may have the potential to displace benzodiazepines altogether and become the safer alternative to help the millions of Americans suffering from anxiety with limited options for safe, effective treatment options. These existing treatments can actually hurt instead of help. We look forward to launching our Phase 3 clinical development program for PH94B next quarter and continuing to push forward in our mission to get it into the hands of those in need as soon as possible."

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing and commercializing differentiated new generation medicines that go beyond the current standard of care for anxiety, depression and other CNS disorders. Each of VistaGen's three drug candidates has a differentiated mechanism of action, an exceptional safety profile in all studies to date, and therapeutic potential in multiple CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

About PH94B

PH94B is an innovative odorless investigational pherine nasal spray with therapeutic potential in multiple mental health disorders involving anxiety or phobia and is designed to have a rapid-onset therapeutic effect. During Phase 2 clinical studies for the potential acute 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.

Forward Looking Statements
Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects, including the potential for successful Phase 3 development of PH94B for SAD. 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: development and approval of PH94B may not be achieved in any market; the FDA may decide that the results of the Company's PH94B Phase 3 clinical program are not sufficient for regulatory approval for acute treatment of anxiety in adult patients with SAD or any other anxiety-related disorder; development of PH94B 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; 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, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B; inadequate and/or untimely supply of PH94B to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B, as well as those risks more fully discussed in the section entitled "Risk Factors" in VistaGen's most recent 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 nine months ended December 31, 2020 as well as discussions of potential risks, uncertainties, and other important factors in either company's other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

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