U.S. FDA Grants VistaGen Therapeutics Fast Track Designation for PH94B for Treatment of Social Anxiety Disorder

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VistaGen's PH94B is the first drug candidate to be granted U.S. FDA Fast Track designation for treatment of social anxiety disorder

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2019 /PRNewswire/ -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for development of the Company's PH94B neuroactive nasal spray for on-demand treatment of social anxiety disorder (SAD).

The FDA's Fast Track process is designed to facilitate the development and review of new treatments for serious conditions with unmet medical need, such as SAD, with the purpose of getting innovative new treatment options to patients sooner. After successful Phase 2 development, VistaGen is preparing PH94B for Phase 3 development. PH94B has potential to be the first fast-acting, non-sedating, as-needed treatment for as many as 20 million individuals in the U.S. suffering from SAD.

"The FDA's grant of Fast Track designation for development of PH94B for SAD, which to our knowledge is the FDA's first Fast Track designation for a SAD drug candidate, is another important regulatory milestone for VistaGen and a key step forward in our development program for PH94B as a new generation anxiolytic. With a high global prevalence of anxiety disorders, including SAD, and alarming increases in dependency, addiction and even deaths associated with misuse of benzodiazepines, the urgency for a new non-addictive, non-sedating, fast-acting, as-needed treatment for SAD and other anxiety disorders is more important now than ever before. Based on clinical studies to date, PH94B, at non-systemic microgram doses, has strong potential to fill the large current treatment gap," said Shawn Singh, Chief Executive Officer of VistaGen.

About VistaGen
VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline is focused on clinical-stage CNS drug candidates with differentiated mechanisms of action, exceptional safety profiles in all clinical studies to date, and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

About PH94B
PH94B is a first-in-class, odorless, rapid-onset (approximately 10 to 15 minutes) CNS neuroactive nasal spray with the potential to be the first FDA-approved, fast-acting, on-demand treatment for millions of Americans who suffer from social anxiety disorder (SAD), with additional potential in peripartum anxiety, pre/postoperative anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Administered at microgram doses, PH94B activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety associated with everyday social and work or performance situations. Following successful Phase 2 development, VistaGen is preparing for Phase 3 clinical development of PH94B for social anxiety disorder. The FDA has granted Fast Track designation for development of PH94B as a treatment for SAD. View more background on SAD and PH94B's mechanism of action.

About Social Anxiety Disorder
Social anxiety disorder (SAD) affects as many as 20 million Americans and is the second most commonly diagnosed anxiety disorder.[1,2] A person with SAD feels symptoms of extreme anxiety or fear in certain social situations, such as meeting new people, dating, being on a job interview, answering a

question in class, or making small talk to a cashier in a store or a networking event at work. Doing everyday things in front of people - such as eating or drinking in front of others or using a public restroom - also causes anxiety or fear. The person is afraid that he or she will be humiliated, judged, and rejected. SAD can significantly compromise academic, social and work life and can predispose individuals to other anxiety disorders, depression and substance use disorders.[3] There is no FDA-approved medication for as-needed, on-demand treatment of SAD. While three antidepressants (two SSRIs and one SNRI) are FDA-approved for treatment of SAD, they take many weeks to work, if they work at all, must be taken chronically, and often present troubling side effects. Individuals affected by SAD need novel treatment alternatives with fast onset therapeutic benefits and far fewer side effects.

About Fast Track Designation

Fast Track is a process designed by the FDA to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track Designation may be eligible to be the subject of more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track Designation may also qualify for a priority, expedited FDA review process, if relevant criteria are met. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. For more information about Fast Track, please visit: https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm.

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 three drug candidates: (i) PH94B for social anxiety disorder and multiple other anxiety disorders; (ii) PH10 for MDD and multiple additional depression disorders and suicidal ideation, and (iii) AV-101 for MDD, neuropathic pain, epilepsy, dyskinesia associated with levodopa therapy for Parkinson's disease and suicidal ideation;. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements 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. Those risks include the following: (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 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 PH94B, PH10 and/or AV-101; (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 preclinical and 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. 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.

[1] Harvard Medical School, 2007. National Comorbidity Survey (NCS). (2017, August 21); Kessler, et al, US National Comorbidity Survey Replication, 2005.

*[2] Anxiety and Depression Association of America, **https://adaa.org/understanding-anxiety/social-anxiety-disorder***

[3] American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.

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