VistaGen Therapeutics Acquires Worldwide License of Phase 3-Ready CNS Drug Candidate from Pherin Pharmaceuticals for As-Needed Treatment of Social Anxiety Disorder

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- *Phase 3-ready asset expands VistaGen's CNS pipeline and complements its neuropsychiatry focus on Major Depressive Disorder (MDD) with AV-101*
- *Novel PH94B nasal spray expected to enter pivotal Phase 3 development for as-needed (PRN) treatment of Social Anxiety Disorder (SAD) in the first half of 2019; positioned to drive a paradigm shift towards rapid-acting treatment of SAD, without risk of addiction*
- *Patents on the use of PH94B nasal spray to treat SAD have been granted in the U.S., Europe, Japan, China, Korea and numerous other countries*

SOUTH SAN FRANCISCO, Calif. and MOUNTAIN VIEW, Calif., Sept. 13, 2018 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders with high unmet need, and Pherin Pharmaceuticals, Inc., a biopharmaceutical company focused on development of novel treatments for neuropsychiatric and neuroendocrine conditions, today announced the signing of a license agreement granting VistaGen exclusive worldwide rights to develop and commercialize PH94B nasal spray, a Phase 3-ready drug candidate for as-needed (PRN) treatment of Social Anxiety Disorder (SAD).

"SAD affects nearly 15 million Americans. Currently, there is no FDA-approved treatment that provides rapid-acting relief, and sedatives used off-label carry with them the risk of addiction and other significant side effects and safety concerns. PH94B clinical data are compelling and support its potential to be a first-in-class, rapid-acting, self-administered, PRN treatment alternative, without sedation, risk of addiction or other safety concerns, for millions affected by SAD in the U.S. and other major markets. This transaction not only expands and diversifies our CNS pipeline to include SAD, but also firmly complements our patent-protected, neuropsychiatry focus on MDD with AV-101 in our ongoing Phase 2 ELEVATE Study," said Shawn Singh, Chief Executive Officer of VistaGen. "We are excited to be working with Pherin's innovative team to develop and commercialize this medically and socially impactful treatment. Our key objective for the PH94B program is to commence our initial pivotal Phase 3 clinical trial of PH94B nasal spray for SAD during the first half of 2019."

Pherin's first-in-class proprietary compounds called "pherines" are synthetic neuroactive steroids that engage nasal chemosensory receptors which, in turn, inhibit nerve circuits mediating behavioral and physiological effects of anxiety. This mechanism of action, the rapid onset of efficacy, and the excellent safety and tolerability profile shown in multiple previous clinical trials, including a pilot Phase 3 feasibility study for evaluating the safety and efficacy of PH94B, make PH94B a novel product candidate for the acute, intermittent and long-term treatment of individuals with SAD.

Dr. Louis Monti, Executive Vice President of Pherin, stated, "This agreement provides a meaningful opportunity to continue our clinical progress and advance our mission to bring novel treatment alternatives to the many individuals affected with SAD. We are confident VistaGen will build upon our earlier clinical studies, which provided impressive evidence of rapid (10-15 minutes) anxiety reduction for subjects with SAD. In all prior clinical studies, PH94B was well tolerated and there were no adverse events associated with nasal spray administration. Our prior clinical studies support the potential of PH94B to be a superior treatment alternative for SAD due to the demonstrated rapid onset of efficacy, route of administration, as-needed dosing convenience, and excellent safety profile compared to other existing therapeutic options which require chronic dosing and have concurrent side effects."

An estimated 12.1% of U.S. adults experience SAD at some time in their lives.[1] SAD is characterized by excessive anxiety about scrutiny or evaluation by others that leads an individual to avoid social situations and/or performance.[2] SAD affects social, academic and work life, and often presents with other anxiety disorders, MDD and substance use disorders, and the onset of SAD generally precedes that of other disorders.[3] Currently, selective serotonin reuptake inhibitors (SSRIs) and selective serotonin-norepinephrine reuptake inhibitors (SNRIs) are FDA-approved for treatment of SAD, but they take weeks to months to work, must be taken chronically and present numerous side effects.

VistaGen has also acquired an option from Pherin to license an additional CNS neuropsychiatry-focused product in Phase 2 development. In connection with the consummation of the license and option agreements, VistaGen issued to Pherin $2.25 million of unregistered common stock (1,630,435 unregistered shares).

About PH94B
PH94B was developed from proprietary compounds called pherines. Administered as a nasal spray, PH94B acts locally on peripheral nasal chemosensory receptors that trigger rapid activation of the limbic system areas of the brain associated with SAD. This mechanism of pharmacological action, the rapid onset of efficacy, and the excellent safety and tolerability profile shown in clinical trials make PH94B an excellent product candidate for the acute intermittent and long-term treatment of individuals with SAD.

About Social Anxiety Disorder
SAD, also called social phobia, affects approximately 15 million American adults and is the third most common psychiatric condition after depression

and substance use.2 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.2 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 AV-101
AV-101 is an oral, non-opioid, non-sedating NMDA receptor glycine B antagonist with potential to be a new at-home treatment for major depressive disorder and multiple CNS indications with high unmet need. AV-101 is currently in Phase 2 clinical development in the United States. ELEVATE is VistaGen's ongoing Phase 2 clinical trial designed to evaluate the efficacy and safety of adjunctive use of oral AV-101 for MDD in individuals with an inadequate response to standard antidepressant therapy with either an FDA-approved SSRI or SNRI. The FDA has granted Fast Track designation to AV-101 for development as a potential adjunctive treatment of MDD.

About VistaGen
VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for depression, SAD and other CNS diseases and disorders with high unmet need. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

About Pherin
Pherin Pharmaceuticals, Inc. is a privately held clinical-stage drug development company that discovered and developed proprietary molecules, "pherines," for the acute and intermittent treatment of neuropsychiatric and neuroendocrine conditions. For more information please visit www.pherin.com.

Forward-Looking Statements
This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of our drug candidates, including AV-101 and PH94B, our intellectual property and commercial protection of our drug candidates, 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 in our clinical development of AV-101 or PH94B that cause us to discontinue further development of either drug candidate, (ii) we may not be able to successfully demonstrate the safety and efficacy of AV-101 or PH94B 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 and/or PH94B, (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 AV-101 or PH94B, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including clinical development of AV-101 and/or PH94B activities described above; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101 or PH94B. 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.

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[1] https://www.nimh.nih.gov/health/statistics/social-anxiety-disorder.shtml

[2] 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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