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VistaGen Therapeutics Acquires Worldwide Rights to Develop and Commercialize PH10, a First-in-Class Intranasally Administered Neuroactive Steroid with Rapid-onset Antidepressant Effects for Major Depressive Disorder Demonstrated in Phase 2a Study

PH10 demonstrated in Phase 2a study significant antidepressant effects without psychological side effects after only one week of administration

SOUTH SAN FRANCISCO, Calif., Oct. 25, 2018 (GLOBE NEWSWIRE) -- 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 Company has exercised its option to acquire from Pherin Pharmaceuticals, Inc. (Pherin) the exclusive license for worldwide rights to develop and commercialize PH10, a first-in-class, intranasally administered neuroactive steroid (a “pherine”), with rapid-onset antidepressant effects for treatment of major depressive disorder (MDD) demonstrated in a phase 2a study. The Company secured the option for PH10 concurrently with its previously announced license agreement with Pherin for worldwide rights to develop and commercialize PH94B, also a first-in-class neuroactive pherine, which VistaGen is preparing for pivotal Phase 3 development as a nasal spray for acute on-demand treatment of social anxiety disorder (SAD).

PH10 activates nasal chemosensory receptors that in turn engage GABA (gamma-aminobutyric acid) and CRH (corticotropin-releasing hormone) neurons in the limbic amygdala system. The activation of these neural circuits is believed to have the potential to lead to a rapid antidepressant effect.

Michael Liebowitz, M.D., a member of VistaGen’s CNS Clinical and Regulatory Advisory Board, has acted as an advisor to Pherin in connection with its clinical trials of PH10 and PH94B and previously presented results for PH10’s eight-week, double-blind, single-

center, 30-patient, Phase 2a study for MDD. Results in the Phase 2a study demonstrated that self-administered doses of PH10 as a nasal spray resulted in significant decreases in depression as measured by the Hamilton Rating Scale for Depression, a widely used clinician-administered depression assessment scale. In this study, PH10 was very well tolerated with minimal side effects.

“After extensive due diligence and guidance from Dr. Liebowitz, we exercised our option to acquire exclusive rights to develop and commercialize PH10 for depression and other CNS diseases,” said Shawn Singh, Chief Executive Officer of VistaGen “Depression is a complicated disease, without a one-size-fits-all solution. Development of promising treatment alternatives with fundamentally different mechanisms of action from current antidepressants is a core competency of our team. We are excited to build upon the notable and steadfast efforts of Dr. Louis Monti, Dr. Liebowitz and Pherin’s entire team in developing PH10 to date. PH10 marks yet another valuable asset in our growing pipeline, with compelling data and complementary to our core focus on developing innovative rapid-onset treatments for MDD beyond ketamine with convenient administration and without debilitating or psychological side effects and safety concerns. We believe that having yet another potentially safe, fast-acting, new generation mechanism of action treatment in play, in addition to AV-101 with its NMDAR GlyB and AMPAR targets, adds strength to strength, allowing us to provide patients with an even broader range of potential solutions to treat MDD, and expands our potential opportunities to monetize our assets to the benefit of our stockholders.”

“Depression is a pervasive mental illness and currently available treatments fall short for many individuals with the disease. Ultra-low doses of intranasal PH10, with its novel mechanism of action, rapid onset activity and excellent safety and tolerability profile demonstrated in a phase 2a study, may represent another life-changing opportunity to address the growing unmet need among individuals suffering from MDD,” stated Dr. Liebowitz.

Pherines inhibit nerve circuits mediating behavioral and physiological effects of anxiety. This mechanism of action, rapid onset of efficacy and excellent safety and tolerability profile have been shown in multiple previous clinical trials, including a pilot Phase 3 feasibility study evaluating the safety and efficacy of PH94B for SAD and Phase 2 feasibility study evaluating the safety and efficacy of PH10 for MDD.

In connection with the consummation of the license and option agreements, VistaGen issued to Pherin $2.0 million of its unregistered common stock (925,926 unregistered shares).

About VistaGen
VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for multiple 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.

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, as well as 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 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 ca. 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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