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AV-101 Stimulates the Formation of New Brain Cells in Nonclinical Studies

SOUTH SAN FRANCISCO, Calif., Jan. 31, 2019 (GLOBE NEWSWIRE) -- VistaGen Therapeutics (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 data from nonclinical studies indicating that its orally available CNS drug candidate, AV-101 (4-chlorokynurenine), promotes hippocampal neurogenesis, the process by which new neurons are formed in a region of the brain that involves high-level functions such as emotions, memory, and spatial navigation and exploration.

“The development of new neurons is a vital part of our mental growth during adulthood, and the exciting results of these nonclinical studies highlight AV-101’s potential to promote adult hippocampal neurogenesis. We believe these results are potentially far-reaching, especially given that enhanced hippocampal cell proliferation provides protection against stress-related psychiatric disorders, including depression,” stated [Shawn Singh, Chief Executive Officer of VistaGen](#).

Robert Schwarcz, Ph.D., Professor of Psychiatry, University of Maryland, Baltimore, and Gloria Hoffman, Ph.D., Professor of Biology, Morgan State University, Baltimore, conducted the rodent studies, which showed increased neurogenesis in the hippocampus following oral daily dosing of AV-101 for 14 -16 days. Neurogenesis was demonstrated by detecting an increased number of cells containing Ki67, a marker of dividing cells, scored by scientists blinded to the treatment groups. These results are consistent with recent observations that sustaining the therapeutic activity of other new generation fast-acting antidepressants, such as ketamine, is dependent on a neurogenic effect. The detailed results of these studies will be presented at an upcoming psychiatry conference.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for multiple CNS diseases and disorders with high unmet need. Each of VistaGen’s CNS pipeline candidates, AV-101, PH10 and PH94B, has potential to provide rapid-onset therapeutic benefits without the psychological and other side effects, safety concerns or inconvenient clinical administration associated with many current and potential new generation medications for CNS diseases and disorders such as major depressive disorder (MDD) and social anxiety disorder (SAD). Each drug candidate in VistaGen’s pipeline is either currently in or has completed Phase 2 clinical development in the United States. AV-101, an oral NMDA receptor glycine B antagonist, is in Phase 2 development,

initially as an adjunctive treatment of MDD. The FDA has granted Fast Track designation for development of AV-101 as both a potential [adjunctive treatment of MDD](#) and as a [non-opioid treatment for neuropathic pain](#). PH10 intranasal, a first-in-class neuroactive steroid with rapid onset effects, is in Phase 2 development for MDD. PH94B intranasal, also a first-in-class neuroactive steroid with rapid onset effects, has completed Phase 2 development and is now being prepared for pivotal Phase 3 clinical development as an on-demand PRN treatment of SAD.

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, potential benefits connected to our drug candidates and our expectations regarding development and commercialization 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 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. 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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