VistaGen Therapeutics Issues Letter to Stockholders as Company Prepares to Initiate AV-101 Phase 2 Study for Major Depressive Disorder

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SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 01/29/18 -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders, today issued a letter to stockholders as the Company prepares to initiate its Phase 2 study of AV-101 for Major Depressive Disorder (MDD).

The full version of the letter to stockholders may be accessed using the following link, or by visiting the Investor Relations section of the Company's website, www.vistagen.com.

https://content.equisolve.net/vistagen/files/docs/shareholder-letter.pdf

In the letter to stockholders, Shawn Singh, Chief Executive Officer, highlights the Company's recent milestones and discusses the impending launch of the Company's Phase 2 clinical study of AV-101 for MDD. VistaGen's AV-101 is an oral new generation antidepressant with a mechanism of action that is fundamentally differentiated from all standard, FDA-approved antidepressants.

"In early-2017, I had the privilege of "Ringing the Bell" at The Nasdaq Stock Market's headquarters in Times Square on behalf of our company. That exciting and unique corporate event proved to be a symbolic prologue to the productive year for VistaGen that followed. The milestones we accomplished in 2017 have strongly positioned us to advance our AV-101 Phase 2 program to new levels throughout this year and next," commented Mr. Singh in the letter to stockholders. "Following a productive meeting with the U.S. Food and Drug Administration (FDA) in the fall of 2017, we achieved two key regulatory milestones before year end. First, in October 2017, the FDA authorized us to proceed, under our Investigational New Drug (IND) application, with our U.S. multi-center Phase 2 clinical study of AV-101 as an oral new generation adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. In addition, in December 2017, the FDA granted us Fast Track Designation for development of AV-101 for treatment of MDD, providing us the opportunity for frequent FDA interactions regarding the most appropriate and efficient development pathway to bring AV-101 to MDD patients. 2017 culminated with the closing of an underwritten public offering that generated gross proceeds of $15 million, enabling us to commence and advance through our Phase 2 study in 2018. I want to thank, again, our underwriters and our new and existing investors for supporting our vision."

Recent Accomplishments:

- Received "green light" from the FDA to launch AV-101 Phase 2 MDD adjunctive treatment study pursuant to our IND.
- Received Fast Track Designation from the FDA for development of AV-101 as an adjunctive treatment for MDD. Fast Track Designation is designed to facilitate the development and review of new treatments for serious conditions, such as MDD, with unmet medical need.
- Continued to strengthen our intellectual property portfolio as the European Patent Office (EPO) granted a patent related to methods of treating depression with AV-101 and certain other neurological indications, and the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,834,801 related to certain methods of production for AV-101.
- AV-101 was featured on the cover of *The Journal of Pain* in October 2017, a peer-reviewed publication of nonclinical studies of the effects of AV-101 in well-established nonclinical models of pain. This article is available at the following link: http://dx.doi.org/10.1016/j.jpain.2017.03.014).
- Closed underwritten public offering that generated gross proceeds of $15 million. Proceeds from the offering enable us to continue research and development, primarily related to our Phase 2 clinical study of AV-101 for MDD.

Mr. Singh continued, "As a result of receiving a "green light" from the FDA, we anticipate launching our AV-101 Phase 2 MDD adjunctive treatment study during the current quarter, with topline data expected to be available during the first half of 2019. In addition, we expect one of our principal collaborators, the U.S. National Institute of Mental Health, to complete its Phase 2 monotherapy study of AV-101 in treatment-resistant MDD patients during 2018. This Phase 2 study is being conducted by Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIMH. AV-101 caught the attention of Dr. Zarate, widely considered a pioneer in ketamine research for MDD, and his team after head-to-head preclinical studies of AV-101 vs. ketamine, ultimately resulting in a Cooperative Research and Development Agreement between VistaGen and the U.S. National Institutes of Health, whereby the NIMH is fully funding and conducting the NIMH Phase 2 monotherapy MDD study of AV-101."

Anticipated Milestones over next 12 to 18 Months:

- *First Quarter of 2018:*
  - Launch our Phase 2 clinical study of AV-101 for MDD with Dr. Maurizio Fava of Harvard University as Principal Investigator; a 180-patient, U.S. multi-center, double-blind, placebo controlled efficacy and safety study evaluating AV-101 as an adjunctive treatment in MDD patients with an inadequate response to standard, FDA-approved

antidepressants.

- *Second Half of 2018:*
  - NIMH AV-101 Phase 2 MDD monotherapy study topline results.
  - Completion of our AV-101 Phase 2 MDD adjunctive treatment study.
- *First Half of 2019:*
  - Launch of AV-101 Phase 2 studies in neuropathic pain and Parkinson's disease levodopa-induced dyskinesia.
  - AV-101 Phase 2 MDD adjunctive treatment study topline results.

VistaGen kicked off 2018 by hosting meetings with current investors, prospective institutional investors and potential strategic partners during the 36th Annual J.P. Morgan Healthcare Conference and 10th Annual Biotech Showcase in San Francisco. Additionally, Mr. Singh participated on a panel with distinguished scientists and clinicians focused on the neuroscience of depression and addiction during the Healthcare Innovation Forum held at the University of California, San Francisco (UCSF) Medical Center in San Francisco.

Mr. Singh concluded, "Reflecting on a productive week in San Francisco, it is apparent to us that a paradigm shift towards a new generation of faster-acting antidepressants, particularly those targeting NMDA and AMPA receptors, is emerging. Throughout 2018, we will remain focused on our core mission - to develop new generation medicines for depression and other CNS disorders affecting millions of people worldwide who do not currently have adequate treatment alternatives. Personally, and professionally, I am motivated and passionate about our mission. I maintain the highest confidence in our strategy and our team, and I anticipate that 2018 will yield even more exciting achievements intended to deliver both life-changing benefits to CNS patients and extraordinary value to our stockholders."

About VistaGen
VistaGen Therapeutics, Inc. (NASDAQ: VTGN), is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other CNS disorders. VistaGen's lead CNS product candidate, AV-101, is in Phase 2 development, initially as a new generation oral antidepressant drug candidate for MDD AV-101's mechanism of action is fundamentally different from all FDA-approved antidepressants and atypical antipsychotics used adjunctively to treat MDD, with potential to drive a paradigm shift towards a new generation of safer and faster-acting antidepressants. AV-101 is currently being evaluated by the U.S. National Institute of Mental Health (NIMH) in a small Phase 2 monotherapy study in MDD being fully funded by the NIMH and conducted by Dr. Carlos Zarate Jr., Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch at the NIMH. VistaGen is preparing to launch a 180-patient Phase 2 study of AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Dr. Maurizio Fava of Harvard University is the Principal Investigator of the VistaGen's AV-101 MDD Phase 2 adjunctive treatment study. AV-101 may also have the potential to treat multiple CNS disorders and neurodegenerative diseases in addition to MDD, including neuropathic pain, epilepsy, Huntington's disease, Parkinson's disease levodopa-induced dyskinesia (PD LID) and other CNS diseases and disorders where modulation of the NMDA receptors, activation of AMPA pathways and/or key active metabolites of AV-101 may achieve therapeutic benefit.

For more information, please visit www.vistagen.com and connect with VistaGen on:

Twitter
LinkedIn
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Forward-Looking Statements
The statements in this press release that are not historical facts may constitute forward-looking statements that are based on current expectations and are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. Those risks and uncertainties include, but are not limited to, risks related to the successful launch, continuation and results of the NIMH's Phase 2 (MDD monotherapy) and/or the Company's planned Phase 2 (MDD adjunctive treatment) clinical studies of AV-101, allowance of patent applications and continued protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the AV-101 Phase 2 clinical development activities described above. These and other risks and uncertainties are identified and described in more detail in VistaGen's filings with the Securities and Exchange Commission (SEC). These filings are available on the SEC's website at www.sec.gov. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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