VistaGen Therapeutics Receives FDA Fast Track Designation for AV-101 for the Treatment of Major Depressive Disorder

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SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 01/03/18 -- 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, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to AV-101 for development as a potential adjunctive treatment for Major Depressive Disorder (MDD). 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 MDD.

"Fast Track Designation is another important regulatory milestone for our AV-101 program for MDD, providing us the opportunity for frequent interactions with the FDA focused on the most appropriate and efficient development pathway to bring AV-101 to MDD patients," said Shawn Singh, Chief Executive Officer of VistaGen. "We are on track to dose the first patient in our AV-101 Phase 2 MDD adjunctive treatment study in the first quarter of 2018."

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 priority review to expedite the 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.

About Major Depressive Disorder

Major Depressive Disorder (MDD) is a common but serious mood disorder in which individuals exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. Over 300 million people worldwide suffer from depression.[1] While antidepressants are widely used for treatment, large scale studies have suggested the U.S. drug-treated MDD market is substantially underserved.[2,3]

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 Major Depressive Disorder (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 and Facebook.

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.

[1] World Health Organization, 2017; Available at http://www.who.int/mediacentre/factsheets/fs369/en/.

[2] Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study),

[3] Decision Resources 2016

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