VistaGen Signs Letter of Intent With National Institute of Mental Health for NIH-Sponsored Phase 2 Clinical Study of AV-101 in Major Depressive Disorder

November 17, 2014

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 11/17/14 -- VistaGen Therapeutics, Inc. (OTCQB: VSTA), a clinical-stage biopharmaceutical company focused on innovative medicine for depression, cancer and diseases and disorders involving the central nervous system (CNS), has signed a Letter of Intent to enter into a Cooperative Research and Development Agreement (CRADA) with the National Institute of Mental Health (NIMH), part of the National Institutes of Health (NIH), to collaborate on a NIMH-sponsored Phase 2 clinical study of VistaGen's lead drug candidate, AV-101, in Major Depressive Disorder, one of the most common mental disorders in the U.S.

The parties anticipate completing the definitive CRADA in December and both commencing and completing the Phase 2 depression study in 2015.

AV-101, an oral, non-sedating, non-hallucinogenic, NMDA receptor (NMDAR) glycineB-site antagonist, is among a new generation of fast-acting, glutamatergic antidepressants with breakthrough potential to treat millions of depression patients who are poorly served by classic antidepressant therapies. Published NIH placebo-controlled clinical trials provide compelling evidence that ketamine, a classic NMDAR channel blocker, produces rapid-onset antidepressant effects. However, the clinical utility of ketamine, which is administered intravenously, and other NMDAR channel blockers has been severely limited by their potential for abuse and dissociative side effects, including hallucinations and schizophrenia-like effects. By regulating the NMDAR rather than blocking it, AV-101 has the potential to achieve the rapid-onset antidepressant effects of ketamine and other classic NMDAR channel blockers, without causing their serious side effects.

The NIH previously awarded VistaGen $8.8 million for its AV-101 preclinical and Phase 1 clinical development programs. In two randomized, double-bind, placebo-controlled Phase 1 safety studies, AV-101 was well tolerated and not associated with any severe adverse events. There were no signs of sedation, hallucinations or schizophrenia-like side effects often associated with ketamine and NMDAR channel blockers with rapid onset antidepressant effects.

Dr. Carlos Zarate, Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIH's National Institute of Mental Health, will be the Principal Investigator of the AV-101 Phase 2 depression study under the proposed CRADA.

"Depression is a global public health concern, affecting over 350 million people worldwide, including millions in the U.S.," said VistaGen Chief Executive Officer, Shawn K. Singh. "We are pleased to be on a specific path headed toward extending our long-standing relationship with the NIH. Collaborating under the new CRADA will provide us and the NIMH with an important near term opportunity to make a major difference in the battle against depression."

About the National Institute of Mental Health
The National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), is the largest scientific organization in the world dedicated to mental health research. NIMH is one of 27 Institutes and Centers of the NIH, the world's leading biomedical research organization. The mission of NIMH is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery and cure. For more information, visit www.nimh.nih.gov.

About VistaGen Therapeutics
VistaGen is a clinical-stage biopharmaceutical company developing innovative medicine for depression, cancer and diseases and conditions involving the central nervous system. VistaGen's lead drug candidate, AV-101, is a novel, potent, oral NMDAR glycineB-site antagonist entering Phase 2 clinical development focused on depression.

With mature, functional human heart cells and liver cells produced using its proprietary pluripotent stem cell technology, VistaGen has developed two novel customized human cellular bioassay systems, *CardioSafe* 3D™ and *LiverSafe* 3D™, for predicting heart toxicity and liver toxicity of new drug candidates long before they are tested in animal or human studies. VistaGen is leveraging its bioassay systems for drug rescue focused on producing new, safer variants of drug candidates previously optimized and tested for efficacy by pharmaceutical companies but terminated before FDA approval due to heart or liver toxicity. VistaGen's initial drug rescue program is focused on a novel therapy for cancer.

Visit VistaGen at http://www.VistaGen.com

Follow VistaGen at http://www.twitter.com/VistaGen

View VistaGen's Facebook page at https://www.facebook.com/VistaGen

Cautionary Statement Regarding 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 VistaGen's successful completion of the CRADA and NIH-sponsored Phase 2 clinical study of AV-101 thereunder, its drug rescue and regenerative medicine activities, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the foregoing activities. 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.

For more information:

Shawn K. Singh, J.D.
Chief Executive Officer
VistaGen Therapeutics, Inc.
www.VistaGen.com
650-577-3613
Investor.Relations@VistaGen.com

Mission Investor Relations
IR Communications
Atlanta, Georgia
www.MissionIR.com
404-941-8975
Investors@MissionIR.com

Source: VistaGen Therapeutics, Inc.

Released November 17, 2014