# Dr. Gerard Sanacora Joins VistaGen's Clinical and Scientific Advisory Board

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**Yale Depression Expert to Advise on Late-Stage Development of Orally-Active AV-101 for Major Depressive Disorder**

SAN FRANCISCO, CA -- (Marketwired) -- 02/05/15 -- VistaGen Therapeutics, Inc. (OTCQB: VSTA), a clinical-stage biopharmaceutical company developing innovative medicine for depression and conditions involving the central nervous system, has added Gerard Sanacora PhD, MD, Professor of Psychiatry at the Yale School of Medicine and Director of the Yale Depression Research Program, to its Clinical and Scientific Advisory Board. Dr. Sanacora will focus on Phase 2 and Phase 3 clinical development of AV-101, VistaGen's orally-active NMDA receptor modulator for treating Major Depressive Disorder (MDD). AV-101 is a unique prodrug candidate that produces, in the brain, 7-chlorokynurenic acid (7-Cl-KYNA), one of the most potent and selective antagonists of the required glycine-binding site of the NMDA receptor, which results in down-regulation of NMDA signaling.

Very positive results in MDD clinical studies of ketamine conducted by the NIH, Yale and others demonstrate rapid relief of depressive symptoms in treatment-resistant MDD patients resulting from down-regulation of the NMDA receptor. These studies provide compelling clinical evidence of the key role of NMDA receptor modulators in a new MDD treatment paradigm, as well as support for AV-101's potential as a novel rapid onset treatment for MDD.

In two randomized, double-blind, placebo-controlled Phase 1 safety studies funded by the National Institutes of Health (NIH), single and repeat-daily oral doses of AV-101 were well tolerated, without any serious adverse events. There were no signs of sedation, hallucinations or the schizophrenia-like side effects often associated with ketamine.

VistaGen has signed a Letter of Intent with the National Institute of Mental Health (NIMH), part of the NIH, to enter into a Cooperative Research and Development Agreement (CRADA) with the NIMH to collaborate with Dr. Carlos Zarate and his colleagues at the NIMH on an NIH-sponsored Phase 2 clinical study of AV-101 in MDD. Under the proposed CRADA, Dr. Zarate, who serves as Chief of the Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the NIMH, will be the Principal Investigator for the study.

"The relatively recent discovery of ketamine's rapid onset antidepressant effects revolutionized our thinking about antidepressant medicine, ushering in development of a new generation of drug candidates with a fundamentally novel mechanism of action compared to the agents that form the mainstay of current depression treatment," said Dr. Sanacora. "VistaGen's AV-101 is among the new generation of antidepressants that modulate the NMDA receptor and may act to normalize glutamate signaling to achieve the rapid and sustained antidepressant benefits of ketamine without ketamine's significant negative side effects."

"Dr. Sanacora and his colleagues at Yale Depression Research Program are among the global leaders in the discovery and elucidation of ketamine's mechanism of action in depression," said Shawn Singh, CEO of VistaGen. "His extensive research and recent clinical experience with the use of ketamine for treating MDD will be highly valuable as we advance AV-101 into late-stage development for depression and other CNS indications."

*About AV-101 and Major Depressive Disorder*

AV-101 is in development by VistaGen for the treatment of multiple CNS indications, including depression (with initial emphasis on MDD), chronic neuropathic pain, epilepsy, Parkinson's disease and Huntington's disease.

Depression is a global public health concern, affecting an estimated 350 million people worldwide, including approximately 7% of U.S. adults. Although numerous antidepressant agents are available, millions of people suffering with depression are poorly served by them. Most of such agents have a mechanism of action which requires several weeks or months before therapeutic benefits are achieved. This several week lag period in onset of therapeutic benefits is widely recognized as one of the major therapeutic limitations of currently approved antidepressants, potentially resulting in substantial morbidity, worsening depression and high risk of suicidal thoughts and behaviors, especially during the first two weeks after starting treatment. As a result, there is an urgent need for a new generation of safe and rapid-acting antidepressant agents. Such agents could have a major impact on public health in the U.S. and worldwide. Strong evidence now indicates that the N-methyl-D-aspartate (NMDA) subtype of glutamate receptors can be successfully targeted as potential rapid-acting agents for the treatment of MDD.

*About VistaGen Therapeutics*

VistaGen is a clinical-stage biopharmaceutical company developing innovative medicine for depression and diseases and conditions involving the central nervous system. VistaGen's lead drug candidate, AV-101, is a new generation orally-available NMDA receptor glycine B-site antagonist entering Phase 2 clinical development for Major Depressive Disorder.

With human heart and liver cells produced using its proprietary pluripotent stem cell technology, VistaGen has developed CardioSafe 3D™ and LiverSafe 3D™, customized bioassay systems for predicting heart toxicity and liver toxicity of new drug candidates before they are tested in animal or human studies. VistaGen is using these bioassay systems for drug rescue focused on producing proprietary new chemical entities (NCEs) that are safer variants of drug rescue candidates previously optimized and tested for efficacy by pharmaceutical companies and others but terminated before FDA approval due to heart or liver toxicity.

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*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 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.

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