

VistaGen Therapeutics Bolsters Clinical and Regulatory Advisory Board with Appointments of Distinguished Key Opinion Leaders in Depression

March 22, 2016

- Sanjay Mathew, M.D., expert in the psychopharmacological management of depressive and anxiety disorders, appointed as Board member -

- Thomas Laughren, M.D., expert in the safety and efficacy of psychiatric drugs with nearly 30 years of experience at the FDA, appointed as Board member -

- Maurizio Fava, M.D., existing member and world renowned expert in depressive disorders and psychopharmacology, appointed as Chairman -

SAN FRANCISCO, March 22, 2016 /PRNewswire/ -- <u>VistaGen Therapeutics Inc.</u> (OTCQB: VSTA) (VistaGen or the Company), a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the central nervous system (CNS), today announced that it has appointed <u>Sanjay Mathew, M.D.</u> and <u>Thomas Laughren M.D.</u> to the Company's Clinical and Regulatory Advisory Board to join its existing members, <u>Gerard Sanacora, M.D., Ph.D.</u> and <u>Maurizio Fava, M.D.</u> The Company also announced today the appointment of Dr. Fava as Chairman of this Board.



"We are thrilled to have attracted a number of the world's leading experts to VistaGen, especially as we continue to explore the clinical benefits of AV-101 for what we believe is potentially a transformative therapeutic advancement for the treatment for individuals with major depressive disorder. These key appointments occur as we prepare for the most important year ahead for VistaGen, with numerous expected clinical and regulatory milestones and key data readouts," commented Shawn Singh, Chief Executive Officer of the Company.

The Clinical and Regulatory Advisory Board is working closely with VistaGen as it continues its ongoing NIH-sponsored Phase 2a clinical study of AV-101, its lead oral prodrug candidate for the treatment of major depressive disorder (MDD), which is expected to report topline data in the first guarter of 2017, and as it prepares to advance AV-101 into a Phase 2b MDD study in the fourth guarter of this year.

"The standard antidepressants and atypical antipsychotics that are available to treat depression today are not effective in two out of three patients," commented Dr. Fava. "This represents a tremendous unmet medical need for continued research to find solutions for individuals and their families living with depression. Given this climate of urgency, there is a great need to advance clinical development programs in order to catalyze a paradigm shift in therapeutic treatment options."

Dr. Fava is acknowledged as a world renowned expert in depressive disorders and psychopharmacology. He is currently Director of the Division of Clinical Research of the Massachusetts General Hospital (MGH) Research Institute, Executive Vice Chair, Department of Psychiatry at MGH, and Executive Director of the MGH Clinical Trials Network and Institute, as well as Slater Family Professor of Psychiatry at Harvard Medical School. For more information on Dr. Fava, please <u>click here</u>.

Dr. Mathew is a leading expert in the psychopharmacological management of adult patients with difficult-to-treat depressive and anxiety disorders and

is currently an Associate Professor of Psychiatry and Behavioral Sciences at Baylor College of Medicine in Houston, Texas. He is the Johnson Family Chair for Research in Psychiatry, Associate Professor with Tenure in the Menninger Department of Psychiatry and Behavioral Sciences, and director of the Mood & Anxiety Disorders Research Program. For more information on Dr. Matthew, please <u>click here</u>.

Dr. Laughren is the former Division Director for the Division of Psychiatry Products, Center for Drug Evaluation and Research at the FDA. Prior to joining the FDA in September, 1983, Dr. Laughren was affiliated with the VA Medical Center in Providence and was on the faculty of the Brown University Program in Medicine. For more information on Dr. Laughren, please <u>click here</u>.

Dr. Sanacora is a Professor of Psychiatry at Yale University, the Director of the Yale Depression Research Program, and the Scientific Director of the Yale-New Haven Hospital Interventional Psychiatry Service. Dr. Sanacora is recognized as a leading translational neuroscientist in the area of mood disorders research. For more information on Dr. Sanacora, please <u>click here</u>.

About AV-101

AV-101 (L-4-chlorokyurenine or 4-CI-KYN) is an orally-available prodrug candidate, currently in Phase 2 development, initially for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants. AV-101 has broad potential utility in other diseases and disorders involving the CNS, including chronic neuropathic pain and epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease. After crossing the blood-brain barrier and reaching brain astrocytes, AV-101 is rapidly and enzymatically converted into 7-chlorokynurenic acid (7-CI-KYNA), a well-characterized, potent and selective antagonist of N-methyl-D-aspartate (NMDA) receptors, acting by blocking the glycine-binding co-agonist site of the NMDA receptor.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company dedicated to developing and commercializing innovative product candidates for patients with diseases and disorders involving the CNS. Our lead product candidate, AV-101, is a next generation, orally available prodrug candidate in Phase 2 development, initially for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressants. AV-101 is currently being evaluated in an ongoing Phase 2a clinical study being conducted by Principal Investigator, Dr. Carlos Zarate, Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of Experimental Therapeutics and Pathophysiology Branch at the National Institute of Mental Health, and Clinical Professor of Psychiatry and Behavioral Sciences, at The George Washington University and fully funded by the U.S. National Institutes of Mental Health.

For more information, please visit www.vistagen.com and connect with the Company 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 VistaGen's successful Phase 2 clinical development of AV-101 for the treatment of MDD and other CNS diseases and disorders, protection of its intellectual property, and the availability of substantial additional capital to support its operations, including the 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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To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/vistagen-therapeutics-bolsters-clinical-and-regulatory-advisory-board-with-appointments-of-distinguished-key-opinion-leaders-in-depression-300239360.html

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