



## VistaGen Therapeutics Appoints Pharmaceutical CNS Drug Development Executive Mark A. Smith M.D., Ph.D. as Chief Medical Officer

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**- Former Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals to lead clinical development of AV-101 in major depressive disorder (MDD) and additional CNS pipeline programs**

SOUTH SAN FRANCISCO, Calif., June 20, 2016 /PRNewswire/ -- [VistaGen Therapeutics, Inc.](#) (NASDAQ: VTGN) (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 it has appointed Mark A. Smith, M.D., Ph.D., as Chief Medical Officer.



"Throughout 2016 we have made great strides in positioning VistaGen for a transformational year, specifically with the addition of [preeminent members to our Clinical and Regulatory Advisory Board](#), the completion of our recently announced [\\$10.9 million financing led by healthcare focused fundamental investors](#), and our graduation to NASDAQ last month," commented Shawn Singh, Chief Executive Officer of the Company.

"The next critical element to achieving our vision is expanding and strengthening our management team to include an industry veteran with extensive CNS clinical development expertise and a broad network. We are incredibly pleased to have attracted Dr. Smith to our team as Chief Medical Officer at such a pivotal time for the Company. His contributions and leadership, both immediately and long term, will be invaluable as we continue to advance our lead CNS product candidate, AV-101, through our ongoing Phase 2a study in MDD and launch our potentially pivotal Phase 2b study in MDD later this year," added Mr. Singh.

Dr. Smith is a research psychiatrist with more than 20 years of experience in basic research and CNS drug development from the lab bench through clinical proof of concept studies. He has been a successful project leader in both discovery and development resulting in approximately 20 investigational new drugs (INDs). Dr. Smith has directed clinical trials aimed at depression, bipolar disorder, anxiety, schizophrenia, Alzheimer's, ADHD and agitation in Phase 1 through Phase 2b and has vast knowledge and expertise in drug discovery and development, translational neuroscience, clinical trial design and regulatory interactions.

"VistaGen has tremendous potential to transform the treatment paradigm in major depressive disorder and significantly improve the standard of care where there truly remains an unmet need. [AV-101 is a promising CNS drug candidate](#) opportunity in MDD and other CNS diseases and is fundamentally differentiated from currently approved treatment alternatives, representing a new generation of antidepressants with faster antidepressant effects without the undesired side effects that are far too common with existing treatments," stated Dr. Smith. "I am honored and thrilled to be joining the VistaGen team at such an important time for the Company alongside leading experts in the field, and I believe that with AV-101, we have the potential to positively change the lives of those who suffer from depression and other CNS diseases," concluded Dr. Smith.

Prior to joining VistaGen, Dr. Smith served as the Clinical Lead for Neuropsychiatry at Teva Pharmaceuticals, where he was accountable for the strategy and clinical development of neuropsychiatric drugs through all phases of development with a focus on schizophrenia, sleep disorders and agitation. Previously, Dr. Smith held a range of director positions including Executive Director of Clinical Development at AstraZeneca Pharmaceutical Company where he led the early development of several novel chemical entities targeting treatment-resistant depression, anxiety and schizophrenia.

Dr. Smith has also held positions as Senior Director of Experimental Medicine of Global Clinical Development and Innovation at Shire Pharmaceuticals and served as Senior Investigator and Principal Research Scientist of CNS Diseases at DuPont Pharmaceuticals. Prior to joining the pharmaceutical industry, he served as a Senior Staff Scientist of the Biological Psychiatry Branch and Senior Staff Fellow of the Clinical Neuroendocrinology Branch at the U.S. National Institute of Mental Health (NIMH).

Dr. Smith received his Bachelors degree and Master of Science from Yale University, his Doctor of Medicine and Doctor of Philosophy in Physiology and Pharmacology from the University of California, San Diego, and completed his residency in the Department of Psychiatry at Duke University Medical Center.

[VistaGen's lead oral prodrug candidate, AV-101](#), is currently being evaluated in an ongoing NIMH-sponsored Phase 2a clinical study for the treatment of major depressive disorder (MDD). The Company expects to report topline data from the Phase 2a clinical study in the second quarter of 2017 and is preparing to advance AV-101 into a Phase 2b MDD study in the fourth quarter of this year.

#### **About AV-101**

AV-101 (L-4-chlorokynurenine or 4-Cl-KYN) is an orally-available prodrug candidate, currently in Phase 2 development, initially for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressants. AV-101 has broad potential utility in other CNS diseases and disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease. AV-101 is orally available, rapidly absorbed through the gut, and then actively transported across the blood-brain barrier. Astrocytes in the brain rapidly convert AV-101 into its active metabolite, 7-chlorokynurenic acid (7-Cl-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. AV-101 is a member of a new generation of fast-acting glutamatergic drug candidates in development for treatment of MDD. These fast-acting drug candidates act through the AMPA receptor pathway increasing the production of nerve connections in the brain - often referred to as "synaptogenesis." The increase in synaptogenesis is thought to be the mechanism by which these new generation fast-acting antidepressant drug candidates provide therapeutic benefit for depression.

#### **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. VistaGen's lead product candidate, AV-101, is a next generation, orally available prodrug 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 NIMH, and fully funded by the NIMH.

For more information, please visit [www.vistagen.com](http://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 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](http://www.sec.gov). VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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