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VistaGen Therapeutics and Baylor College of Medicine Collaborate on First-Step Study to Test VistaGen's AV-101 for Potential Anti-Suicidal Effects in Veterans

Veterans from Operation Enduring Freedom, Operation Iraqi Freedom and Operation New Dawn to Participate in Study

SOUTH SAN FRANCISCO, Calif. and HOUSTON, Aug. 13, 2018 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ:VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders, and Baylor College of Medicine (Baylor), today announced that VistaGen and Baylor are collaborating on a first-step [study with healthy volunteer Veterans](#) to test potential anti-suicidal effects of VistaGen's AV-101.

A total of 12 healthy volunteer Veterans from either Operation Enduring Freedom, Operation Iraqi Freedom or Operation New Dawn will be administered single doses of AV-101, at 720 mg and 1440 mg and placebo, over three weeks in a randomized, double-blind, cross-over study to define a dose-response relationship between AV-101 and relevant biomarkers related to NMDA function and others possibly related to suicidality. Dr. Marijn Lijffijt of Baylor will be Principal Investigator. VistaGen and the U.S. Department of Veterans Affairs (VA) entered into a Material Transfer Cooperative Research and Development Agreement (MT CRADA) regarding clinical trial material for this study, and government funding will be provided for substantially all other study costs.

"The number of Veterans who take their own life is tragic and staggering, averaging 20 suicides per day," said [Shawn Singh, Chief Executive Officer of VistaGen](#) "These statistics are not acceptable. As suicide prevention is a vital mission of Baylor and VistaGen, our goal for this initial study is to set the stage to advance our collective efforts to help Veterans fight suicidal ideation on a long-term basis. Suicide is a national public health concern that affects people everywhere, and we must do more to raise awareness and pursue novel faster-acting and safe treatments to help those who continue to suffer from both debilitating depression and suicidal ideation. The status quo for treatment is just not working, and individuals, especially Veterans, need better alternatives."

"Baylor College of Medicine and [Dr. Sanjay Mathew](#), a member of [VistaGen's CNS Clinical](#)

[and Regulatory Advisory Board](#), share an important mission to find better treatment alternatives for Veterans who suffer from depression, suicidal ideation and other CNS indications,” added Dr. Lijffijt. “The suicide rate is two times higher in Veterans than in citizens of equivalent age and gender. A priority for suicide prevention is to come up with novel treatment targets for safe and rapidly acting interventions to impact acute suicidality, which is not adequately addressed with current treatments. This study is the first step in working to revolutionize the way that we treat suicidal ideation and behaviors. Our expectation is to complete the dosing by the end of September 2018, with top-line results from the study expected by year end. The results of this initial study in healthy volunteer Veterans could lead to a Phase 2 study involving AV-101 and Veterans who are battling suicidal ideation or behaviors.”

AV-101 is currently undergoing two separate, more advanced [Phase 2 clinical studies](#) for the treatment of major depressive disorder.

About Suicide

According to the World Health Organization (WHO), every year approximately 800,000 people worldwide take their own life and many more attempt suicide.¹ Suicide is a major public health concern in the United States as rates of suicide have been increasing for both men and women and across all age groups. Suicide is the 10th leading cause of death in the U.S. and is one of just three leading causes that are on the rise.² The Center for Disease Control and Prevention (CDC) reported that in the U.S. the age-adjusted rate of suicide increased by 24 percent between 1999 and 2014.³ The number of U.S. citizens who die by suicide is, since 2010, higher than those who die in motor vehicle accidents. People of all genders, ages, and ethnicities can be at risk for suicide and suicidal behavior is complex and there is no single cause. In fact, many different factors contribute to someone making a suicide attempt, including, but not limited to, depression, other mental health disorders or substance abuse disorder; certain other medical conditions; chronic pain; prior suicide attempt; and family history of mental disorder or substance abuse.⁴

Additionally, it has been found that the Veteran population is at significantly higher risk for suicide. After adjusting for differences in age, risk for suicide was 19 percent higher among male Veterans compared with U.S. civilian adult men and 2.5 times higher among female Veterans compared with U.S. civilian adult women.⁵ Despite these many risk factors, suicide is not inevitable for those that have one or more risk factor(s). Starting a conversation, reducing stigma, providing support and resources and working to develop safe and novel treatments for those in need can help prevent suicide and save the lives of many.

Veterans who are in crisis or having thoughts of suicide, and those who know a Veteran in crisis, should call the [Veterans Crisis Line](#) for confidential support 24 hours a day, seven days a week, 365 days a year at 800-273-8255 and press 1, chat online at [VeteransCrisisLine.net/Chat](#) or send a text message to 838255.

To reach the [National Suicide Prevention Lifeline](#) network, please call 1-800-273-8255 (available 24 hours every day). Learn more about VA’s suicide-prevention resources and programs at [www.mentalhealth.va.gov/suicide_prevention/](#).

Additional materials can be found on VistaGen’s Resources page [here](#).

About AV-101

AV-101 is an oral, non-opioid, non-sedating NMDA receptor glycine B (NMDAR GlyB) antagonist that offers the potential to be a new at-home treatment for multiple CNS indications with high unmet medical need. AV-101 is currently in Phase 2 clinical development in the United States for treatment of major depressive disorder. [ELEVATE](#) is VistaGen's ongoing Phase 2 clinical trial designed to evaluate the efficacy and safety of adjunctive use of AV-101 for MDD in patients with an inadequate response to standard antidepressant therapy with either an FDA-approved selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI). AV-101's [mechanism of action](#) (MOA) is fundamentally different from that of all current FDA-approved SSRIs and SNRIs, most of which, if effective for a given patient, take many weeks to achieve therapeutic benefits.

AV-101 may also have the potential to treat neuropathic pain, epilepsy, Parkinson's disease levodopa-induced dyskinesia, suicidal ideation and other CNS diseases and disorders where NMDA receptor modulation and AMPA pathway activation may achieve therapeutic benefits. The FDA has [granted Fast Track designation](#) to AV-101 for development as a potential adjunctive treatment of MDD.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for depression and other CNS diseases and disorders with high unmet need. For more information, please visit www.vistagen.com and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

About Baylor College of Medicine

Baylor College of Medicine (www.bcm.edu) in Houston is recognized as a premier academic health sciences center and is known for excellence in education, research and patient care. It is the only private medical school in the greater southwest and is ranked 16th among medical schools for research and 5th for primary care by U.S. News & World Report. Baylor is listed 21st among all U.S. medical schools for National Institutes of Health funding and number one in Texas. Located in the Texas Medical Center, Baylor has affiliations with seven teaching hospitals and jointly owns and operates Baylor St. Luke's Medical Center, part of CHI St. Luke's Health. Currently, Baylor trains more than 3,000 medical, graduate, nurse anesthesia, physician assistant and orthotics students, as well as residents and post-doctoral fellows. Follow Baylor College of Medicine on Facebook (<http://www.facebook.com/BaylorCollegeOfMedicine>) and Twitter (<http://twitter.com/BCMHouston>).

Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of AV-101, the potential of AV-101 for the treatment of MDD and various other CNS diseases and disorders and our intellectual property and commercial protection of AV-101 constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to

differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients in our ELEVATE study or other clinical studies, including the VA-sponsored first-step study of AV-101 for suicidal ideation, that cause us to discontinue further development of AV-101, (ii) we may not be able to successfully demonstrate the safety and efficacy of AV-101 at each stage of clinical development, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future AV-101 studies, and ongoing or future preclinical and clinical results may not support further development of AV-101 or be sufficient to gain regulatory approval to market AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of the ELEVATE study, the VA-sponsored first step study or the initiation, timing and progress of future AV-101 clinical trials, and our ability to proceed with further clinical studies or to obtain marketing approval, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for AV-101, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including clinical development of AV-101 activities described above; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101 or other product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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¹ <http://www.who.int/news-room/fact-sheets/detail/suicide>

² <https://www.cdc.gov/media/releases/2018/p0607-suicide-prevention.html>

³ [Curtin SC, Warner M, Hedegaard H. Increase in suicide in the United States, 1999–2014. NCHS data brief, no. 241. Hyattsville, MD: National Center for Health Statistics. 2016.](#)

⁴ <https://www.nimh.nih.gov/health/topics/suicide-prevention/index.shtml>

⁵ <https://www.mentalhealth.va.gov/docs/2016suicidedatareport.pdf>



Source: VistaGen Therapeutics, Inc.