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VistaGen Therapeutics Achieves Target Patient Enrollment in the ELEVATE Study of AV-101 as an Adjunctive Treatment for Major Depressive Disorder

Company on Track to Report Topline Data Before Year End

SOUTH SAN FRANCISCO, CA / ACCESSWIRE / August 15, 2019/ VistaGen Therapeutics (NASDAQ:VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, announced today that the Company has achieved completion of target patient enrollment (n = 180) in its Phase 2 ELEVATE clinical trial. ELEVATE is a multi-center, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101, VistaGen's novel, oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist, as an adjunctive treatment (together with an FDA-approved oral antidepressant (AD)) for major depressive disorder (MDD) in adult patients with an inadequate therapeutic response to their current AD.

VistaGen expects to report topline results from the Phase 2 ELEVATE study before the year end 2019.

"We are very encouraged to reach this important milestone in our Phase 2 development program for AV-101 in MDD. Achieving target patient enrollment puts us one step closer to redefining the standard of care for a large and growing number of individuals who are unable to reduce their symptoms of depression with their current antidepressant alone," said Shawn Singh, Chief Executive Officer, VistaGen. "We look forward to completing the ELEVATE study in the near term and reporting topline data by year end."

About AV-101

AV-101 (4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with multiple CNS diseases and disorders, including chronic neuropathic pain, epilepsy, MDD, levodopa-induced dyskinesia (LID) and many others. AV-101 is an oral prodrug of 7-Cl-KYNA which binds uniquely at the glycine site of the NMDA receptor. With its exceptional safety profile in all studies to date, AV-101 has potential to be a new at-home treatment for multiple large market CNS indications where current treatments are inadequate to meet high unmet patient needs. VistaGen is currently focused on potential development of AV-101 for MDD, neuropathic pain, suicidal ideation and dyskinesia associated with levodopa treatment for Parkinson's disease. The FDA has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain.

About ELEVATE
Among VistaGen's objectives for AV-101 in MDD is to replace atypical antipsychotics in the current MDD drug treatment paradigm and redefine the standard of care for individuals who are unable to reduce their symptoms of depression with their current antidepressant alone. The ELEVATE study is an ongoing U.S. multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study to evaluate the efficacy and safety of adjunctive use of AV-101 in adult MDD patients who have an inadequate response to standard FDA-approved antidepressant therapy, either a selective serotonin reuptake inhibitor (SSRI), a serotonin norepinephrine reuptake inhibitor (SNRI), or bupropion. The primary endpoint of the study is the change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS-10) total score.

About Major Depressive Disorder (MDD)
MDD is a serious neurobiologically-based mood disorder, affecting approximately 16 million adults in the U.S., according to the NIMH. Individuals diagnosed with MDD exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities, for more than a two-week period, as well as impaired social, occupational, educational or other important functioning which has a negative impact on their quality of life. Globally,

MDD affects nearly 300 million people of all ages and is the leading cause of disability worldwide.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's pipeline includes three differentiated, clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with an exceptional safety profile in all clinical studies to date and therapeutic potential in multiple large and growing CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development and commercialization of our three drug candidates, (i) AV-101 for MDD, and specifically the completion of our ELEVATE study, NP, LID and suicidal ideation; (ii) PH94B for SAD; and (iii) PH10 for MDD. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements 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 during our clinical development of any product candidate, including in AV-101 during the ELEVATE study, that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development, including for AV-101 during the ELEVATE study, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, the ELEVATE study or other further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities, and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our 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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