



VistaGen Therapeutics Issued Two Key U.S. Patents for Treatment of Depression with AV-101

June 13, 2018

SOUTH SAN FRANCISCO, Calif., June 13, 2018 (GLOBE NEWSWIRE) -- [VistaGen Therapeutics, Inc.](#) (NASDAQ:VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders, today announced that the U.S. Patent and Trademark Office (USPTO) has issued the following two key U.S. patents related to AV-101, VistaGen's oral new generation CNS product candidate in Phase 2 development for treatment of Major Depressive Disorder (MDD):

- [U.S. Patent No. 9,993,453](#) related to AV-101's therapeutic uses to treat depression; and
- [U.S. Patent No. 9,993,450](#) related to AV-101's oral dosage formulations.

The two new AV-101 U.S. patents above will not expire until at least 2034.

"The issuance of these U.S. patents is a fundamental advancement of our plan to secure commercial exclusivity for AV-101 in the world's major pharmaceutical markets," stated [Shawn Singh, Chief Executive Officer of VistaGen](#). "Our primary goal is to develop and commercialize AV-101 as an oral new generation antidepressant for convenient at-home use. We believe oral administration provides greater flexibility for location of care, which is optimal for people suffering with MDD, and the potential of rapid onset of symptom reduction can provide life-changing benefits for millions of people. Today's U.S. patent issuances and the initiation earlier this year of ELEVATE, our U.S. multi-center Phase 2 study of AV-101 in MDD, are milestones in our AV-101 MDD program, each a significant step forward in our efforts to provide new treatment alternatives to millions of people battling depression and its consequences every day."

About AV-101

AV-101 is an oral N-methyl-D-aspartate receptor glycine B (NMDAR GlyB) antagonist in Phase 2 clinical development in the United States. [ELEVATE](#) is VistaGen's ongoing Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety of adjunctive use of oral 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). Dr. Maurizio Fava of Massachusetts General Hospital and Harvard Medical School is the Principal Investigator of VistaGen's ELEVATE study.

AV-101 belongs to a new generation of investigational medicines in neuropsychiatry known as glutamate receptor modulators having the potential to treat MDD faster than current FDA-approved SSRIs and SNRIs. AV-101's [mechanism of action](#) (MOA) is fundamentally different from all current FDA-approved SSRIs and SNRIs for depression, most of which, if effective for a given patient, take many weeks to achieve therapeutic benefits. AV-101 targets a receptor for glutamate, the most prevalent neurotransmitter in the brain. AV-101 inhibits NMDA receptor activity, activates AMPA pathways and has the potential to achieve ketamine-like antidepressant effects as an oral drug candidate for at-home use that does not cause ketamine's side effects and safety concerns. 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 modulation of the NMDA receptors and activation of AMPA pathways 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. VistaGen's lead CNS product candidate, AV-101, is an oral NMDAR GlyB antagonist in Phase 2 clinical development in the United States for MDD and other CNS indications.

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 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 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 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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Source: VistaGen Therapeutics, Inc.

Released June 13, 2018