



## VistaGen Therapeutics Expands European Patent Protection for AV-101 for Treatment of Depression and Dyskinesia associated with Levodopa Therapy for Parkinson's Disease

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SOUTH SAN FRANCISCO, Calif., Oct. 28, 2019 /PRNewswire/ -- [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, today announced that the European Patent Office (EPO) has granted the Company a second patent for therapeutic uses of AV-101, its oral NMDA (N-methyl-D-aspartate) receptor glycine site antagonist. The new patent expands the set of claims relating to treatment of depression and dyskinesia (involuntary or diminished voluntary muscle movements) associated with levodopa therapy for Parkinson's disease. The patent will be in effect until at least 2034.



# VistaGen® Therapeutics

AV-101 (4-CI-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA receptor modulators. The NMDA receptor is a pivotal receptor in the brain and its abnormal function is associated with numerous CNS diseases and disorders. AV-101 is in Phase 2 clinical development in the United States, initially for treatment of Major Depressive Disorder (MDD). Among VistaGen's key objectives for AV-101 in MDD is to replace atypical antipsychotics in the current MDD drug treatment paradigm and to redefine the standard of care for individuals who are unable to reduce symptoms of depression with their current oral antidepressant alone. VistaGen recently completed patient dosing in the ELEVATE study, its 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 their current oral antidepressant therapy. The Company remains on track to report top line results of the ELEVATE study before the end of 2019.

In previously announced positive preclinical studies of the effects of AV-101 in a widely-used non-human primate model for reproducing motor complications of Parkinson's disease (PD) and dyskinesia observed in PD patients treated with levodopa, AV-101 significantly ( $p = 0.01$ ) reduced levodopa-induced dyskinesia without affecting the timing, extent, or duration of the antiparkinsonian benefits of levodopa. AV-101's therapeutic effects were similar to those generally observed with amantadine therapy, but AV-101 did not cause adverse effects experienced with amantadine.

### **About Major Depressive Disorder (MDD)**

MDD is a serious neurobiologically-based mood disorder affecting nearly 300 million globally and is the leading cause of disability worldwide, according to the World Health Organization. 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.

### **About Parkinson's Disease (PD)**

PD is the second most common neurodegenerative disease worldwide, affecting approximately one million people in the U.S. and ten million people worldwide, according to the Parkinson's Foundation. Although there is no "one-size-fits-all" description of PD, PD is a complex neurodegenerative disorder that occurs when brain cells that make dopamine, a chemical that coordinates movement, stop working or die, resulting in progressive deterioration of voluntary motor control. Classic PD motor symptoms include muscular rigidity, resting tremor, and postural and gait impairment. Typically, PD patients present with a combination of motor and non-motor symptoms. Non-motor symptoms may include cognitive impairment, sleep disorders, pain and fatigue. There is currently no medication to slow, delay, stop or cure PD, and currently available treatments are symptomatic. Treatment of motor symptoms of PD with oral levodopa, introduced about 50 years ago, remains the gold standard treatment.

### **About Levodopa-Induced Dyskinesia (LID)**

LID is a disorder that affects people with PD who are treated with the current gold standard of care, oral levodopa, for an extended period of time. Oral levodopa remains the most effective therapy for motor symptoms of PD. However, after continuous long-term use (longer than five years), many PD patients experience LID. Although clinical manifestations of LID are diverse, LID is commonly associated with abnormal involuntary movements, including chorea and dystonia. These motor complications tend to become more severe as PD progresses and as the duration of levodopa treatment is extended, until the impact of LID may compromise the advantage of treatment with levodopa. PD treatment with levodopa is routinely delayed due to concerns over LID. Once LID develops, levodopa-treated PD patients may be faced with a choice between immobility due to untreated (and uncontrolled) PD, or mobility with the associated LID.

### **About AV-101**

AV-101 (4-CI-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-CI-KYNA, a potent and selective full antagonist of the glycine co-agonist 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, non-sedating 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 PD. 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 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 clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with a differentiated mechanism of action, 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](http://www.vistagen.com) and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

### **Forward-Looking Statements**

Various statements in this release 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, dyskinesia associated with levodopa therapy for PD 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, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that we may not be able to successfully demonstrate the safety and efficacy of AV-101 at each stage of clinical development; 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; 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; we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for AV-101; we may not have access or be able to secure substantial additional capital to support our operations, including clinical development of AV-101 activities described above; and we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101 or other product candidates, as well as those risks 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](http://www.sec.gov). In addition, any forward-looking statements represent our views only as of today 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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