VistaGen Announces Positive Preclinical Data Supporting AV-101's Potential for Treating Neuropathic Pain Comparable to Pregabalin (Lyrica(R)), without its Side Effects

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- ***New preclinical data involving pregabalin are consistent with peer-reviewed data involving gabapentin previously published in The Journal of Pain***

SOUTH SAN FRANCISCO, CA / ACCESSWIRE / May 30, 2019 / VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression, social anxiety disorder and other central nervous system (CNS) diseases and disorders with high unmet need, today announced positive results of recent preclinical studies of the effects of AV-101, VistaGen's oral NMDA receptor glycine site antagonist, compared to pregabalin (Lyrica®[1]) in the Chung ligation model of pain, an accepted gold standard preclinical model for chronic neuropathic pain caused by nerve damage.

These preclinical studies were conducted under contract in the laboratory of Tony L. Yaksh, Ph.D., Professor in Anesthesiology at the University of California San Diego School of Medicine. This work demonstrated that AV-101 had a significant dose-response with similar efficacy in a rat model of a mononeuropathy as compared to pregabalin (Lyrica), which was used as an active comparator. Similar positive results involving AV-101 in this preclinical model, but using gabapentin (Neurontin®[2]) as an active control, were previously peer-reviewed and published in *The Journal of Pain*[3]. Detailed results of these new studies will be presented at an upcoming scientific conference.

"In this new preclinical study examining AV-101's analgesic and behavioral profile compared to pregabalin, AV-101 demonstrated robust analgesic effects, similar to pregabalin, but fewer side effects as measured in the rotarod assay," reported H. Ralph Snodgrass, Ph.D., VistaGen's Chief Scientific Officer. "This study provides further support of AV-101's potential to treat debilitating neuropathic pain, without causing the burdensome side effects and safety concerns associated with the medications currently used by millions of Americans to treat neuropathic pain, such as drowsiness, dizziness and risk of abuse."

The U.S. Food and Drug Administration has granted Fast Track designation for the development of AV-101 as a non-opioid treatment of neuropathic pain.

About Neuropathic Pain

Neuropathic pain (NP) affects approximately 33 million people in the United States (excluding patients with back pain).[4] It is characterized by a steady burning "pins and needles" or "electric shock" sensation that results in abnormal neuronal function after nerve damage resulting from traumatic injuries, viral infections, certain medications, or metabolic conditions such as diabetes. Current treatments for neuropathic pain include antidepressants, anticonvulsants (such as gabapentin and pregabalin), and opioids, among others. However, current medications may offer inadequate efficacy, have limiting side effects, and be associated with abuse.

About AV-101

AV-101 (4-Cl-KYN) belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA 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, major depressive disorder, Parkinson's disease levodopa-induced dyskinesia and many others. AV-101 is an oral prodrug of 7-Cl-KYNA which binds uniquely at the glycine site of the NMDA receptor and has potential to be a new at-home treatment for multiple CNS indications with high unmet need. 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 depression, social anxiety disorder and other CNS diseases and disorders with high unmet need. VistaGen's pipeline includes three CNS drug candidates, AV-101, PH10, and PH94B. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn and Facebook.

[1] Marketed by Pfizer in the U.S. as Lyrica®.

[2] Marketed by Pfizer in the U.S. as Neurontin®.

[3] **Yaksh, T.L., et al. (2017). Characterization of the Effects of L-4-Chlorokynurenine on Nociception in Rodents. The Journal of Pain 18:1184-1196.**

[4] DiBonaventura, M.D., Sadosky, A., Concialdi, K., Hopps, M., Kudel, I., Parsons, B., et al. (2017). The prevalence of probable neuropathic pain in the US: results from a multimodal general-population health survey. J Pain Res 10:2525-2538.

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 drug candidates, including AV-101 for neuropathic pain, all of which 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 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, (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 our drug candidates, including AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, 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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