



Vistagen Therapeutics Successfully Completes Final Phase 1 Safety Study of AV-101

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Lead Prodrug Candidate Is Being Developed for Chronic Neuropathic Pain

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 01/23/13 -- VistaGen Therapeutics, Inc. (OTCQB: VSTA), a biotechnology company applying stem cell technology for drug rescue, predictive toxicology and drug metabolism screening, today announced the successful completion of its final Phase 1 safety study of AV-101, a novel orally available prodrug candidate being developed for treatment of multiple conditions involving chronic neuropathic pain. The study results indicate that AV-101 is safe and well tolerated, with favorable bioavailability and pharmacokinetics.

"This important confirmation of AV-101's safety is the final step in our Phase 1 program for AV-101," said Shawn K. Singh, JD, VistaGen's Chief Executive Officer. "With \$8.8 million of funding from the National Institutes of Health (NIH) and outstanding strategic development and regulatory support from Cato Research Ltd., we have successfully completed the required studies enabling Phase 2 clinical development of AV-101 for multiple large market neurological diseases and conditions. In addition, recent data from the NIH suggest that the same neural pathway modified by AV-101 may be useful for treating depression. Launching a broad strategic collaboration to advance development and commercialization of AV-101 is among our key goals in 2013."

About the Final AV-101 Phase 1 Safety Study

VistaGen's final AV-101 Phase 1 safety study was a randomized, double-blind, placebo-controlled, dose-escalation clinical trial conducted at the University of California, San Diego (UCSD). The study involved three cohorts of healthy volunteers, each receiving multiple daily treatments of one of three dose levels of orally administered AV-101 over a 14-day period. The primary objectives of the study were to evaluate the safety, tolerability and pharmacokinetics (PK) of three different daily doses of AV-101 compared to placebo controls. A total of 46 healthy volunteers completed the study. The oral administration of AV-101 was safe and well tolerated by all subjects at all three dose levels tested. In addition, the PK of AV-101 was fully characterized across the range of three dose levels in the study. The data indicate that AV-101 had good bioavailability and a favorable PK profile.

"The primary safety and tolerability endpoints of the Phase 1 program were met. This is a very safe compound with no observed side effects," commented Mark S. Wallace, MD, Chair of the Division of Pain Medicine, Department of Anesthesiology at UCSD and the principal investigator of the study. "AV-101 is an exciting prodrug compound that acts through a promising mechanism to treat pain. I am excited to move this compound into Phase 2 studies for the treatment of pain."

About AV-101

Aimed at multi-billion dollar neurological disease and disorders and depression markets, AV-101, also known as "L-4-chlorokynurenine" (4-Cl-KYN), is a novel, orally available prodrug that is converted in the brain into an active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), which regulates an important neurotransmitter in the brain called the N-methyl-D-aspartate (or NMDA) receptor. A synthetic analogue of kynurenic acid, a naturally occurring neural regulatory compound, 7-Cl-KYNA is one of the most potent and selective blockers of the regulatory GlyB-site of the NMDA receptor.

VistaGen's AV-101 IND application covers clinical development for neuropathic pain. In addition to neuropathic pain, VistaGen expects the results of its Phase 1 clinical program to be useful for supporting the development of AV-101 for other neurological disorders including depression and epilepsy.

About VistaGen Therapeutics

VistaGen is a biotechnology company applying human pluripotent stem cell technology for drug rescue, predictive toxicology and drug metabolism screening. VistaGen's drug rescue activities combine its human pluripotent stem cell technology platform, Human Clinical Trials in a Test Tube™, with modern medicinal chemistry to generate novel, safer chemical variants (Drug Rescue Variants) of once-promising small molecule drug candidates. These are drug candidates discontinued by pharmaceutical companies, the U.S. National Institutes of Health (NIH) or university laboratories, after substantial investment in discovery and development, due to heart or liver toxicity or metabolism issues. VistaGen uses its pluripotent stem cell technology to generate early indications, or predictions, of how humans will ultimately respond to new drug candidates before they are ever tested in humans, bringing human biology to the front end of the drug development process.

VistaGen's small molecule prodrug candidate, AV-101, has completed Phase 1 development for treatment of neuropathic pain. Neuropathic pain, a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system, affects millions of people worldwide.

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Cautionary Statement Regarding Forward Looking Statements

The statements in this press release that are not historical facts may constitute forward-looking statements that are based on current expectations and are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. Those risks and uncertainties include, but are not limited to, risks related to the success of VistaGen's stem cell technology-based drug rescue, predictive toxicology and metabolism screening activities, further clinical development and commercialization of AV-101 for chronic neuropathic pain or any other disease or condition, its ability to enter into strategic predictive toxicology, metabolism screening, drug rescue and/or drug development and commercialization collaborations and/or licensing arrangements with respect to AV-101 or any one or more drug rescue variants, risks and uncertainties relating to the availability of substantial additional capital to support its research, drug rescue, development and commercialization

activities, and the success of its research and development plans and strategies, including those plans and strategies related to AV-101 and any drug rescue variant identified and developed by VistaGen. These and other risks and uncertainties are identified and described in more detail in VistaGen's filings with the Securities and Exchange Commission (SEC). These filings are available on the SEC's website at www.sec.gov. VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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