



VistaGen Therapeutics Presents Highlights of Its Human Stem Cell-Derived "Micro-Heart" Cardiotoxicity Assay at NIH Symposium on Cardiovascular Regenerative Medicine

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SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 10/05/11 -- VistaGen Therapeutics, Inc. (OTCBB: VSTA), a biotechnology company applying stem cell technology for drug rescue and cell therapy, announces a poster presentation of its research and development activities leading to validation of its human stem cell-derived "Micro-Heart" cardiotoxicity bioassay system, CardioSafe 3D™, at the fourth Symposium on Cardiovascular Regenerative Medicine hosted by the National Institutes of Health's ("NIH") National Heart, Lung and Blood Institute. The poster was presented by Dr. Ralph Snodgrass, VistaGen's President and Chief Scientific Officer, at the NIH symposium held in Bethesda, Maryland on October 4 - 5, 2011.

The research and development work presented by Dr. Snodgrass underscores the advances VistaGen's versatile pluripotent stem cell technology platform, Human Clinical Trials in a Test Tube™, is driving in the areas of predictive toxicology and drug safety screening. Screening methods currently employed by the pharmaceutical industry to measure the potential toxicity of drug candidates do not accurately predict the cardiac effects of many new drug candidates. There is a growing recognition in the field that existing methods suffer from the use of either animal models, which respond differently than humans to many drugs, or cell lines that are engineered, transformed, non-human and/or of non-cardiac lineage and are typically focused on the effects of the drug candidate on a single cardiac ion channel. These methods yield both false positive and false negative results leading to important implications for patient safety and costly project terminations during clinical development. Human pluripotent stem cells have the potential to address these limitations by permitting the generation of functional human cardiac cells that express ion channels and auxiliary proteins relevant to the accurate measurement of cardiac function and evaluation of the possibility of long-term cardiac abnormalities.

"Cardiotoxicity has been implicated in almost 30% of drug withdrawals in the United States over the last 30 years," said Dr. Ralph Snodgrass, President and Chief Scientific Officer of VistaGen. "Our human stem cell-derived 'Micro-Heart' cardiotoxicity assay, CardioSafe 3D™, will contribute to the efficient and rapid identification of safer drugs before valuable resources are lost developing drug candidates with toxicity issues that are undetected until human clinical trials are in progress or even after FDA approval resulting in withdrawal from the market."

The poster describes work conducted by VistaGen's scientists in collaboration with scientists at ChanTest Corporation in Cleveland, Capsant Neurotechnologies in Southampton (in the UK), and the laboratory of Dr. Gordon Keller at the University Health Network's McEwen Centre for Regenerative Medicine in Toronto. The research described combines optimized stem cell cardiac differentiation protocols, a novel 3-dimensional culture system, and traditional electrophysiological measurements to assess drug-related safety data. The system, called a "Micro-Heart" Cardiotoxicity Assay, was validated by measuring the dose-dependent effects on cardiomyocyte cell viability and electrophysiological responses, as measured by patch clamp and field potential assays, of twelve compounds with known cardiac cytotoxicity or electrophysiology effects.

These drugs included Class III antiarrhythmic compounds, mixed ion channel compounds, antihistamines, sodium and calcium channel blockers, as well as antineoplastic agents. The observed action potential Vmax values of these highly enriched cardiomyocytes was approximately 3-6x higher than values reported in the literature, suggesting a more normal high-level sodium channel density in these cardiomyocytes. Expected dose-dependent effects of typical hERG channel blockers on QT interval were observed, as well as dose-dependent effects of mixed ion channel drugs. In addition, direct dose-dependent drug cytotoxicity could also be measured.

The data described in the poster presentation have demonstrated that VistaGen's human stem cell-derived "Micro-Heart" cardiotoxicity bioassay system is highly reproducible with very strong concordance with the in vivo cardiac effects of multiple classes of compounds. This work further supports VistaGen's Human Clinical Trials in a Test Tube™ platform by demonstrating its strong applicability for preclinical cardiac safety screening, with greater sensitivity and predictive power than conventional animal models for compounds known to induce lethal arrhythmias. VistaGen is developing this platform for proprietary applications in drug rescue screening, cell therapy and regenerative medicine, and the validation of its stem cell-derived human cardiac cell-based assays represents another major step forward in demonstrating the clinical relevance and power of the platform.

To view the complete abstract of the presented poster, please visit the investors section of the VistaGen website at www.vistagen.com.

VistaGen is a recipient of the "Novel Reprogrammed Cells for Differentiation into Cardiomyocytes" grant funded by The National Heart, Lung, and Blood Institute ("NHLBI"). The goal of this grant is to explore novel approaches of creating patient-specific iPS cells. NHLBI's Symposium on Cardiovascular Regenerative Medicine brings together experts in stem cell biology and clinical cardiovascular medicine to discuss research progress in the field. Through a discussion of emerging science in the field and its clinical applications, the symposium's goal is to foster the translation of stem cell biology and research into human clinical applications. The Institute is part of the National Institutes of Health of the US Department of Health and Human Services.

About VistaGen Therapeutics

VistaGen Therapeutics is a biotechnology company applying human pluripotent stem cell technology for drug rescue and cell therapy. Drug rescue involves the combination of human pluripotent stem cell technology with modern medicinal chemistry to generate new chemical variants of once promising small molecule drug candidates that pharmaceutical companies have discontinued during preclinical or early clinical development due to heart or liver toxicity, despite positive efficacy data demonstrating their potential therapeutic and commercial benefits. VistaGen plans to use its pluripotent stem cell technology, including its human stem cell-derived "Micro-Heart" cardiotoxicity bioassay, CardioSafe 3D™, to generate early indications, or predictions, of how humans will ultimately respond to new drug candidates before they are ever tested in humans.

In parallel with its drug rescue activities and in collaboration with Dr. Gordon Keller in Toronto, VistaGen is preparing to initiate pilot preclinical cell therapy programs involving the proprietary stem cell differentiation and cell production capabilities of its Human Clinical Trials in a Test Tube™ platform.

Additionally, VistaGen will begin a Phase 1b clinical study of AV-101, a small molecule drug candidate for treatment of neuropathic pain, before the end of 2011. This study includes testing AV-101 in healthy volunteers using the intradermal capsaicin model 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 approximately 1.8 million people in the U.S. alone. VistaGen plans to initiate Phase 2 clinical studies of AV-101 in the fourth quarter of 2012. VistaGen is also exploring additional opportunities to leverage its current Phase 1 clinical program to enable additional Phase 2 clinical studies of AV-101 for epilepsy, Parkinson's disease and depression. To date, VistaGen has been awarded over \$8.5 million from the U.S. National Institutes of Health (NIH) for development of AV-101.

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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 regulatory approvals and the success of VistaGen's ongoing clinical studies, including the safety and efficacy of its drug candidate, AV-101, the failure of future drug rescue and pilot preclinical cell therapy programs related to VistaGen's stem cell technology-based Human Clinical Trial in a Test Tube™ platform, and, specifically, its human stem cell-derived "Micro-Heart" cardiotoxicity bioassay, CardioSafe 3D™, the strength and scope of its intellectual property portfolio, its ability to enter into drug rescue collaborations, risks and uncertainties relating to the availability of substantial additional capital to support its patent prosecution, research, development and commercialization activities, and the success of its research, development, regulatory approval, marketing and distribution plans and strategies, including those plans and strategies related to AV-101 and any drug rescue variants 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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