VistaGen Therapeutics Enhances Predictive Liver Toxicology and Drug Metabolism Bioassay System -- LiverSafe 3D(TM)

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Novel Human Stem Cell-Based Bioassay Based on VistaGen's Human Clinical Trials in a Test Tube(TM) Platform

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 11/13/12 -- VistaGen Therapeutics, Inc. (OTCBB: VSTA) (OTCQB: VSTA), a biotechnology company applying stem cell technology for drug rescue, predictive toxicology and drug metabolism screening, today announced a significant advance in its development of LiverSafe 3D™, a human liver cell-based bioassay system designed to predict liver toxicity and drug metabolism issues in connection with the Company's drug rescue activities.

Shawn K. Singh, VistaGen's Chief Executive Officer, stated, "As we have done with CardioSafe 3D™, our stem cell-based bioassay system for predictive heart toxicity screening and drug rescue, we are developing LiverSafe 3D™ to change the game in drug development -- to generate clinically predictive liver toxicology and liver metabolism data at the front end of the drug development process, long before standard animal and human testing."

VistaGen's LiverSafe 3D™, together with optimized culture protocols and without the need for any purification, is now capable of producing differentiated populations of cells containing greater than 70% albumin-positive human hepatocytes (liver cells), and greater than 40% of these hepatocytes express the mature CYP3A4 drug metabolizing enzyme. CYP3A4 is a crucial enzyme in adult liver functions and widely viewed as an important functional marker for adult stem cell-derived hepatocytes. This enzyme is responsible for metabolizing over 50% of the drugs approved by the FDA. With purification, LiverSafe 3D™ can obtain hepatocyte populations approaching 90% expressing the CYP3A4 enzyme.

H. Ralph Snodgrass, PhD, VistaGen's President and Chief Scientific Officer, commented, "Our LiverSafe 3D™ bioassay system involves custom-designed liver cells that are engineered to indicate when CYP3A4 is produced, and to allow the selection for mature cells expressing CYP3A4. On a per cell basis, LiverSafe 3D™ hepatocytes express functional CYP3A4 drug metabolism activity that approaches 25% to 40% of the metabolic activity seen with some commercial batches of human hepatocytes. We believe that this frequency and activity far exceed most, if not all, comparable data reported in the literature for stem cell-derived human hepatocytes. Our continuing R&D efforts are focused on further improvements of LiverSafe 3D™ to the point where it is comparable in all aspects to commercial human liver cells."

Primary human cadaveric hepatocytes are well established, and, in many cases, are required by the FDA as an in vitro drug development tool for predicting liver toxicity, drug metabolism and drug-drug interactions. However, the demand for primary human cadaveric hepatocytes for these studies exceeds the available supply. Even ignoring the supply limitations and high costs, primary human cadaveric hepatocytes have several undesirable attributes for drug development applications, including (1) the health of the donor and quality of the cadaveric hepatocytes received in the laboratory are often not ideal, (2) even high quality cadaveric hepatocytes rapidly lose critical hepatocyte functions important to drug development, and (3) batches of human cadaveric hepatocytes exhibit unknown and uncontrolled genetic variations that can dramatically influence the outcome of drug responses and metabolism. These, and other limitations of primary human cadaveric hepatocytes, highlight a widespread understanding of the pharmaceutical industry's need for a clinically predictive and readily accessible alternative for drug development. VistaGen is developing LiverSafe 3D™ to meet that need.

About VistaGen Therapeutics

VistaGen Therapeutics is a biotechnology company applying human pluripotent stem cell technology for drug rescue and novel pharmaceutical assays for predictive heart and liver toxicology and drug metabolism screening. VistaGen's drug rescue activities are focused on combining its human pluripotent stem cell technology platform, Human Clinical Trials in a Test Tube™, with modern medicinal chemistry to generate new chemical variants (Drug Rescue Variants) of once-promising small-molecule drug candidates. These are drug candidates discontinued due to heart or liver toxicity after substantial investment and development by large pharmaceutical companies, the U.S. National Institutes of Health (NIH) or university laboratories. 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.

Additionally, VistaGen's orally-available, small molecule drug candidate, AV-101, is completing 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. To date, VistaGen has been awarded over $8.5 million from the 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 the development and commercialization of LiverSafe 3D™, CardioSafe 3D™, or drug rescue variants derived from the Company's stem cell technology platform, successful completion of the Company's Phase 1 clinical development program for AV-101, the failure of the Company's future drug rescue and predictive toxicology programs involving its stem cell technology-based Human Clinical Trial in a Test Tube™ platform, the Company's ability to enter into third-party research, development and drug rescue collaborations, risks and uncertainties relating to the availability of substantial additional capital to support the Company's research,

development and commercialization activities, and the success of its research and development plans and strategies, including plans and strategies related to AV-101 and any drug rescue variant identified and developed by VistaGen or its collaborators. These and other risks and uncertainties are identified and described in more detail in VistaGen's filings with the 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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