



## VistaGen Joins HESI's Cardiac Safety Committee and Working Groups

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### Industry-Led Consortium Developing a Novel Paradigm for Cardiac Safety Evaluation of New Drugs

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/22/14 -- VistaGen Therapeutics, Inc. (OTCQB: VSTA), a biotechnology company applying pluripotent stem cell technology for drug rescue and regenerative medicine, today announced that it has become a member of the Cardiac Safety Technical Committee, Cardiac Stem Cell Working Group, and Proarrhythmia Working Group of the Health and Environmental Sciences Institute (HESI), a global branch of the International Life Sciences Institute (ILSI), whose members include most of the world's largest pharmaceutical and biotechnology companies.

Using mature cardiomyocytes (heart cells) differentiated from human pluripotent stem cells, VistaGen developed its *CardioSafe* 3D™ bioassay system to predict the *in vivo* cardiac effects, both toxic and non-toxic, of small molecule drug candidates with greater speed and precision than the long-established, surrogate safety models most often used in drug development. VistaGen's pluripotent stem cell-derived heart cells and *CardioSafe* 3D are key components of its *Human Clinical Trials in a Test Tube*™ platform and drug rescue programs.

"We look forward to collaborating with leading pharmaceutical, biotechnology, academic, and regulatory members of the HESI's Cardiac Safety Technical Committee, and related working groups, to help advance, among other goals, the FDA's CIPA initiative, which is focused on developing innovative preclinical systems for cardiac safety assessment during drug development," said Ralph Snodgrass, Ph.D., VistaGen's President and Chief Scientific Officer.

#### *About ILSI*

The International Life Sciences Institute (ILSI) is a nonprofit, worldwide organization whose mission is to provide science that improves human health and well-being and safeguards the environment. It achieves this mission by fostering collaboration among experts from academia, government, and industry on conducting, gathering, summarizing, and disseminating science.

For more information on ILSI, visit [www.ilsilife.org](http://www.ilsilife.org)

#### *About HESI and the FDA's CIPA Initiative*

HESI was established in 1989 as a global branch of the International Life Sciences Institute (ILSI) to provide an international forum to advance the understanding of scientific issues related to human health, toxicology, risk assessment, and the environment. In 2002, HESI was recognized by the United States government as a publicly supported, tax-exempt organization, independently chartered from ILSI. HESI's scientific programs bring together scientists from around the world from academia, government, industry, and research institutes to address and reach consensus on scientific questions that have the potential to be resolved through creative application of intellectual and financial resources.

The goal of the FDA's Comprehensive In Vitro Proarrhythmia Assay (CIPA) initiative is to develop a new paradigm for cardiac safety evaluation of new drugs that provides a more comprehensive assessment of proarrhythmic potential by (i) evaluating effects of multiple cardiac ionic currents beyond hERG and ICH S7B (inward and outward currents), (ii) providing more complete, accurate assessment of proarrhythmic effects on human cardiac electrophysiology, and (iii) focusing on Torsades de Pointes proarrhythmia rather than surrogate QT prolongation alone.

For more information on HESI, visit [www.hesiglobal.org](http://www.hesiglobal.org) For more information on the CIPA initiative, visit [www.ilsixtra.org/hesi/science/cardiac/cipa/SitePages/Home.aspx](http://www.ilsixtra.org/hesi/science/cardiac/cipa/SitePages/Home.aspx)

#### *About VistaGen Therapeutics*

VistaGen™ is a stem cell company headquartered in South San Francisco, California and focused on drug rescue and regenerative medicine. We believe *better cells lead to better medicine*™ and that the key to making better cells is precisely controlling the differentiation of human pluripotent stem cells, which are the foundation cells of the human body. For over 15 years, our stem cell research and development teams and collaborators have focused on controlling the differentiation of human pluripotent stem cells to produce multiple types of mature, functional, adult cells, with emphasis on human heart and liver cells for drug rescue applications. Our drug rescue model involves using our human cell-based *in vitro* bioassay systems, *CardioSafe* 3D and *LiverSafe* 3D, and medicinal chemistry to generate novel, safer variants (*Drug Rescue Variants*™) of promising small molecule drug candidates (*Drug Rescue Candidates*™) previously tested extensively and validated by pharmaceutical or biotechnology companies for their therapeutic (efficacy) and commercial potential, but discontinued after substantial investment due to unexpected safety concerns relating to the heart or liver.

With \$8.8 million of grant funding awarded from the U.S. National Institutes of Health, VistaGen has successfully completed Phase 1 clinical development of AV-101, it's an orally available small molecule prodrug candidate aimed at the multi-billion dollar neurological disease and disorders market, including neuropathic pain, a serious and chronic condition causing pain after an injury or disease of the peripheral or central nervous system, epilepsy and depression.

Visit VistaGen at [www.VistaGen.com](http://www.VistaGen.com), follow VistaGen at [www.twitter.com/VistaGen](https://twitter.com/VistaGen) or view VistaGen's Facebook page at [www.facebook.com/VistaGen](https://www.facebook.com/VistaGen).

#### *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 activities or further clinical development and commercialization of AV-101, its ability to enter into strategic partnering arrangements, and risks and uncertainties relating to the availability of substantial additional capital to support its research, drug rescue and drug development activities. 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](http://www.sec.gov). VistaGen undertakes no obligation to publicly update or revise any forward-looking statements.

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