April 3, 2013

Next-Generation Circulating Tumor Cell Test Demonstrates High Efficiency and Accuracy in New Study

First Results of Collaboration Between Veridex, LLC and Massachusetts General Hospital Published in Science Translational Medicine

RARITAN, N.J., April 3, 2013 /PRNewswire/ -- Veridex, LLC (Veridex) announced today that the first study of the company's next-generation circulating tumor cell (CTC) technology, developed in collaboration with researchers at Massachusetts General Hospital (MGH), has been published in *Science Translational Medicine*. The collaboration, initially announced in January 2011, has led to the development of a next-generation CTC (or "liquid biopsy") technology that offers enhanced specificity and sensitivity and enables more extensive characterization of captured cells.

The new technology tests for CTCs from the blood of cancer patients using advanced microfluidic separation techniques integrated with innovative magnetic sorting to isolate a broad spectrum of rare circulating cancer cells. This technology will allow physicians to get information about a patient's cancer at the time treatment is being administered, one of the key components to enabling personalized medicine.

Results from the *in vitro* study showed the integrated system enabled the processing of large blood volumes with high throughput and efficiency, and also allowed for the ability to isolate CTCs from both epithelial and non-epithelial cancers.

In the study, the technology was used to identify the presence of CTCs in patients with cancers of the lung, prostate, pancreas, breast, as well as melanoma.

"Veridex is proud to have introduced CELLSEARCH®, the first and only FDA-cleared CTC test, and we're excited to work with the team at Massachusetts General Hospital on our next-generation test," said Nicholas C. Dracopoli, Ph.D., Vice President and Head of Oncology Biomarkers, Janssen Research & Development, LLC. "Together, Veridex and the MGH team bring more than 25 years of experience in rare cell technology to this project. We're encouraged by the positive results from this study and the potential role this technology may play in helping to advance physicians' ability to monitor their patients and develop more personalized treatment approaches."

"These results show the possibility of its use for patients in 'real time' as they are receiving treatment. We hope that this next-generation CTC technology will become an everyday tool for doctors treating patients with cancer," said Mehmet Toner, Ph.D., director of the BioMicroElectroMechanical Systems Resource Center in the Massachusetts General Hospital.

How It Works

The system used two modes of immunomagnetic sorting to isolate CTCs: a positive selection mode to identify and tag target CTCs based on expression of the epithelial surface marker EpCAM ("epithelial cell adhesion molecule"), and a negative selection mode, in which the blood sample is depleted of leukocytes by tagging them with specific antibodies. The test's ability to isolate CTCs in this manner allows for RNA-based, single cell molecular characterization and expression analysis of CTCs. It will also allow for the test to be used in a broader range of cancers, including cells undergoing epithelial-mesenchymal transition (EMT) and cancer stem cells.

The technology integrates three sequential processes in a single automated system to capture clinically significant CTCs. First, after whole blood samples have been labeled with magnetic beads, the system separates nucleated cells, including CTCs and white blood cells, from red blood cells and platelets with minimal cell loss. Next, the system aligns nucleated cells in a single file within a sorting channel. Finally, the magnetically tagged cells are deflected into a collection channel for identification. These three integrated functions replace the need for separate cell lysis (break down), centrifugation and sorting steps.

About Circulating Tumor Cells

Circulating tumor cells are cancer cells that have detached from the tumor and are found at extremely low levels in the bloodstream. The value of capturing and counting CTCs is evolving as more research data is gathered about the utility of these markers in monitoring disease progression and potentially guiding personalized cancer therapy.

About Veridex, LLC

Veridex, LLC, a Johnson & Johnson company, is an organization dedicated to providing physicians with high-value diagnostic oncology products. Veridex's *in vitro* diagnostic products may significantly benefit patients by helping physicians make more informed decisions that enable better patient care. Veridex's Clinical Research Solutions provide tools and services that may be used for the selection, identification and enumeration of targeted rare cells in peripheral blood for the identification of biomarkers, aiding scientists in their search for new, targeted therapies. For more information, visit www.veridex.com.

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