ApoCell, Inc. publishes data demonstrating capabilities of ApoStream ™ device for improved capture of circulating tumor cells (CTCs)

HOUSTON (Nov, 2011) --- Clinical trial data presented this week by ApoCell, Inc. demonstrated the capabilities of its new ApoStream™ device to isolate higher numbers of circulating tumor cells (CTCs) in blood and to effectively detect more cancer cell types than currently available commercial methods.

CTCs have long been known to exist in cancer patients' blood. Correlation has been established between the number of CTCs and disease progression, and CTC's are often used as a "liquid biopsy" – a means of studying the state of a patient's disease without invasive surgical procedures. Current commercial technologies are limited in both the number of CTCs that can be isolated, problems which ApoCell hopes to address with their ApoStream™ platform.

ApoCell's President and CEO Darren Davis, Ph.D and his research team presented the findings from the first phase of clinical trials with the ApoStream™ platform in San Francisco this week at the AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics.

The trials included CTC testing of blood samples from prostate, breast, non-small cell lung cancer and melanoma patients. Testing also involved normal donor blood as control samples. There were no false positives for CTCs among control specimens, demonstrating ApoStream's specificity.

Initial findings from the trials show positive CTC counts were obtained in 90% of lung cancer samples with cell counts ranging from 0 – 2,104. CTCs were detected in 93% of prostate cancer samples with cell counts ranging from 0 – 3,490. CTCs were detected in 100% of the breast cancer and melanoma samples, with CTC counts ranging from 176 – 968 in breast cancer patients and 4 – 3120 in melanoma patients.

"Because of ApoStream's higher CTC isolation and capture capability, it provides greater opportunities for downstream analysis of the cancer cells," Davis said. "This has significant implications for cancer treatment selection as well as assessing effectiveness and developing personalized therapies."

Davis pointed out that the most widespread commercial CTC detection technology to date - and the only FDA cleared CTC diagnostic platform - depends on the presence of the EpCAM antigen on the surface of the cancer cell, while ApoStream's technology does not. "ApoStream™ can detect cancer cells regardless of their level of EpCAM expression, which is why it can detect a wide array of cancer cell types," he said.

Instead of utilizing an antibody-dependent capture method, ApoStream™ employs a process known as dielectrophoresis field flow fractionation (DEP-FFF), using a low level electrical field of varying frequencies to enable the separation of viable cancer cells from blood. The technology was invented by scientists at the University of Texas MD Anderson Cancer Center's Laboratory of Diagnostic Microsystems and licensed exclusively to ApoCell. Davis also noted that EpCAM-negative CTCs were recovered in all tested breast cancer patient specimens from the trial, illustrating that ApoStream™ isolates cancer cells independent of their EpCAM status.

"We're currently building ApoStream™ into Phase 1, Phase 2, and Phase 3 clinical trials based on the results we have seen and believe it has great potential," Davis said.

In keeping with that potential, ApoCell was awarded a $2.9 million contract in August of this year from SAIC-Frederick Inc. (SAIC-F) in support of the National Cancer Institute, for the development and delivery of 12 alpha prototype units of ApoStream™. This was the first commercial order for the revolutionary new cancer diagnostic device and ApoCell expects to deliver the alpha prototype units to SAIC-F for NCI use by early 2013.

About ApoCell

Based in Houston, Texas, ApoCell (www.apocell.com) is a privately-held specialty clinical research company. Founded in 2004, the firm is a leader in molecular biomarker detection and analysis and leverages its expertise in the areas of oncology, diabetes, molecular diagnostics and drug development to measure biomarker signatures in clinical trial subjects. The company's proprietary methods provide early proof of mechanism of action and monitor the effectiveness of various types of drugs by measuring biomarker expression patterns in biopsies, blood and rare cell types. The company's facilities are CLIA-certified and compliant with applicable FDA regulations. Since inception, the company has participated in over 120 Phase I, II, and III clinical cancer drug trials for more than 80 sponsor clients worldwide. In 2011, the firm was named to the Inc. 5000 List of America's Fastest Growing Companies.

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