Cytori Reports Stem & Regenerative Cells from Body Fat Produce Statistically Significant Improvement in Heart Function in Chronic Ischemia Trial

SAN DIEGO, May 07, 2010 (BUSINESS WIRE) -- The first clinical trial of adipose (fat) tissue-derived stem and regenerative cells (ADRCs) for the treatment of no-option chronic heart disease patients showed the following: the procedure was safe and feasible; it demonstrated a statistically significant improvement in maximum oxygen consumption (MVO_2) and patients' aerobic capacity measured as metabolic equivalents (METS); and reduced the extent of infarct size in the left ventricle. Stem and regenerative cells were prepared and made available at the point-of-care using the Celution(R) System, the proprietary cell processing device developed by trial sponsor Cytori Therapeutics (NASDAQ:CYTX). More detailed information on this study and the results from a separate study in heart attack patients also reported today may be found at the following link: cytoritx.presslift.com/cardiacdata.

The study, referred to as the PRECISE trial, is a multi-center 27 patient, double-blind, placebo-controlled, dose-escalation European study in patients with chronic myocardial ischemia, a severe form of heart disease. Highlights of the study's six-month outcomes are as follows:

- Liposuction and cell injection were safe in these severely compromised patients, with no serious adverse events (arrhythmia or major adverse cardiac events)
- MVO_2 showed a statistically significant improvement from baseline to six-months in the cell treated group as compared to placebo. MVO_2 is a clinically relevant prognostic factor in heart disease and is commonly used as a contributing measure to stratify patients for heart transplant
    - The results showed absolute increase (improvement) in MVO_2 by 0.6 mL/kg/min in the treated group versus 2.8 mL/kg/min decrease (worsening) in the placebo group from baseline to six-months, based on matched-pair analysis. This difference was statistically significant ($p < 0.05$). This analysis excludes two patients whose follow up MVO_2 results were not available
    - For the entire cohort of patients, mean MVO_2 improved from 16.6 mL/kg/min at baseline to 17.2 mL/kg/min at six-months in cell-treated patients, and worsened from 19.0 mL/kg/min to 15.5 mL/kg/min in the placebo group
- METS (metabolic equivalent), a measure of the patient's aerobic capacity, improved by 0.2 points from baseline to six-months in the cell treated group compared to a decrease of 0.8 points from baseline to follow up in the placebo group based on matched-pair analysis; the difference was statistically significant ($p < 0.05$)
- The percent of left ventricle infarcted, the portion of the heart not receiving blood to support pumping, decreased (improved) by 3.0% in the cell treated group compared to an increase (worsening) of 5.2% in the placebo group, an absolute difference of 8.2%
- Improvements in New York Heart Association Functional Class, which classifies the severity of heart disease on a scale of one to four, were observed in 63% of patients treated with cells as compared to observed in 33% of patients in the placebo group

Primary six-month outcomes from the study were presented today, at the 7th International Symposium on Stem Cell Therapy & Cardiovascular Innovation in Madrid, Spain. The study was led by Principal Investigator of the Study Francisco Fernández-Avilés M.D. PhD, Professor of Medicine and Chief of Department of Cardiology at Hospital Universitario Gregorio Marañón (Madrid) with the collaboration of Co-Principal Investigator Emerson C. Perin, MD, PhD, Director, Clinical Research for Cardiovascular Medicine, and Medical Director, Stem Cell Center, Texas Heart Institute. Patrick W. Serruys, MD, PhD, Professor of Interventional Cardiology at the Thoraxcentre, Erasmus University Hospital participated as co-investigator in this trial.

"ADRCs have emerged as a promising cell-based therapy for heart disease," said Dr. Aviles. "They possess two distinct advantages compared to cells from alternative sources. First, a high number of cells can be quickly accessed and prepared for reinjection using Celution(R). Second, they yield a mixed population of cells rich in several growth factors and cytokines, believed to impart several repair mechanisms. The results of the PRECISE trial are really encouraging and fully consistent with preclinical evidence that ADRCs improve perfusion and performance of chronic ischemic heart failure by producing new vessels."

"We showed the Celution(R)-based procedure is safe and feasible in severely compromised patients and improved various measures, which are suggestive of efficacy," said Dr. Perin. "MVO_2 in particular is one of the most widely accepted predictors of clinical outcomes, including mortality and the requirement for a heart transplant. We are excited to report statistically significant improvement in MVO_2 and its corollary METS in this study, which is highly suggestive of the power of these adipose-derived stem and regenerative cells."

"Cytori is extremely appreciative to the patients who participated as well as to the investigators and hospital staff," added Marc H. Hedrick, M.D., president of Cytori. "As additional data are compiled from PRECISE, we will incorporate the findings into the design and protocol of a planned chronic heart disease pivotal study to be funded by Cytori or a partner."

As part of the procedure, a small amount of fat tissue was removed from each patient's abdomen. Using the proprietary Celution(R) System, stem and regenerative cells were quickly separated from each patient's fat tissue and concentrated at the point-of-care while the patients were prepared for catheterization and injection. Immediately thereafter, using the NOGA(TM) System, made by Biologic Delivery Systems Group, a J&J company, a three dimensional image was created to guide the injection of cells into the injured (ischemic) regions of the heart. This six-month analysis was performed by combining the outcomes of all of the cell treated patients in the study. Further evaluation is being performed on all patients at 12 and 18 months as well as by comparing high and low cell dose cohorts.

About Cytori

Cytori is a leader in providing patients and physicians around the world with medical technologies that harness the potential of adult regenerative cells from adipose tissue. The Celution(R) System family of medical devices and instruments is being sold into the European and Asian cosmetic and reconstructive surgery markets but is not yet available in the United States. Our StemSource(R) product line is sold globally for cell banking and research applications. www.cytori.com

Cautionary Statement Regarding Forward-Looking Statements

This press release includes forward-looking statements regarding events, trends, business prospects and particularly the PRECISE clinical study results, which may affect our future operating results and financial position. Such statements, including, but not limited to, those regarding improvements in patient outcomes, the significance of the improvements in the cell treated groups, other benefits believed to be imparted by the treatments discussed above, and our ability to design and implement a protocol in potential subsequent studies, are all subject to risks and uncertainties that could cause the results of a more comprehensive clinical study to differ materially from those presented above. Some of these risks and uncertainties include, but are not limited to, risks related to statistical power of the PRECISE study, the need for further clinical studies to confirm the above referenced outcomes, inherent risk and uncertainty in the costs and potential variability of outcomes in a pivotal chronic heart disease study, regulatory uncertainties regarding the collection and results of clinical data, and dependence on third party performance, as well as other risks and uncertainties described under the "Risk Factors" in Cytori's Securities and Exchange Commission Filings on Form 10-K and Form 10-Q. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

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