Stemedica Ischemic Tolerant Stem Cells Produce Significant Improvement in Cardiac Function After Heart Attack

The Associated Press

Transplanted ischemic tolerant mesenchymal stem cells (itMSC) developed by Stemedica Cell Technologies, Inc., a leader in adult allogeneic stem cell manufacturing, research and development, produced significant improvement in the pumping function of the left ventricle in patients who had experienced a heart attack. The study was presented at the 26th American College of Cardiology (ACC) meeting in Chicago, March 26, 2012.

Transplanted ischemic tolerant mesenchymal stem cells (itMSC) developed by Stemedica Cell Technologies, Inc., a leader in adult allogeneic stem cell manufacturing, research and development, produced significant improvement in the pumping function of the left ventricle in patients who had experienced a heart attack. The study was presented at the 26th American College of Cardiology (ACC) meeting in Chicago, March 26, 2012 by Daniyar Jumaniyazov, MD, PhD and Nikolai Tankovich, MD, PhD, President and Chief Medical Officer of Stemedica.

Forty five patients who had experienced an acute myocardial infarct underwent reperfusion by stent and after being carefully matched, were divided into a treatment and a control group. The treatment group received intravenous infusion of Stemedica itMSCs on day seven; the control group received normal saline. At the end of three months, those in the treatment group experienced an 11 point improvement in the ejection fraction of the left ventricle (the amount of blood pumped with each heart contraction) in comparison with the control group. This level of improvement restored the treatment group's ejection fraction to normal levels. In comparison, the control group showed a level of improvement expected with standard of care; however, the ejection fraction remained below normal. In addition, the treatment group had statistically significant improvements in two blood markers of inflammation; levels of C-reactive protein and BNP were lower in the treated group. Patients in the stem cell treatment group also had improvement in quality of life indicators. Magnetic Resonance Imaging (MRI) performed day six and again day 30 in the treatment group showed significant decreases in lesion size. Patients in this study will be followed for one year.

Commenting on the study, Nabil Dib, MD, MSc, FACC, Director, Clinical Cardiovascular Cell Therapy & Associate Professor of Medicine at the University of California, San Diego noted, "Data from this early clinical trial are very promising. If these results continue as patients are followed longer term, and if they can be replicated in a larger clinical trial, then Stemedica's ischemic tolerant allogeneic mesenchymal stem cells may well play an important role in the treatment of heart disease." According to Jackie See, MD, FACC, an interventional cardiologist specializing in stem cell research in Fullerton, California, "These are impressive

results and provide a great deal of hope for patients with heart disease. Stents open up the narrowed blood vessels. With the addition of stem cells, we can potentially rescue some of the damaged myocardial cells, promote new blood vessel growth, decrease inflammation, and strengthen the damaged muscle. I can see a day in the near future when intravenous itMSC administration becomes part of the standard of care following an acute myocardial infarct." Noting that not all stem cells are created equally, Dr. Tankovich raises a key point about the research, "This study highlights the importance of using allogeneic stem cells specifically manufactured to be effective in the toxic tissue environment following a heart attack.

In vitro, we know that our itMSCs secrete more of the important healing factors in response to ischemia. Our cells also retain their 'steminess', remaining undifferentiated and potent throughout the manufacturing process. They also pass the most stringent tests for infectious disease, acute and chronic toxicity and tumorigenecity, and they are immune privileged. These are some of the advantages of using a well characterized, homogeneous population." Dr. See notes that the importance of expanding cells from a single, healthy young donor versus using autologous bone marrow cells from the same patient. "Results from a large multi-center study supported by the National Heart, Lung, and Blood Institute, presented at the ACC, showed that bone marrow derived stem cells taken from older, sicker patients were not very effective in improving heart function. This is understandable, because these stem cells no longer have the power to differentiate, migrate, engraft and secrete the factors that are necessary for wound healing. So the patients who most need the treatment do not have potent stem cells to accelerate the cardiac healing process." Dr. Tankovich further notes that providing enough stem cells for thousands of patients who could benefit from Stemedica's itMSC treatment is not an issue. "With our advanced expansion techniques, with only four passages, from a single tissue donation, we can treat half a million patients." The placebo controlled blinded Phase II clinical trial was conducted according to ICH guidelines at the National Medical Research Center (NMRC) in Astana, Kazakhstan. The NMRC is Kazakhstan's premier medical research institute and internationally known for initial assessment and treatment of returning NASA astronauts. Based upon the outcome of this trial, NMRC is planning a Phase III trial using Stemedica's itMSCs for a larger population.

Stemedica is planning a parallel Phase II clinical trial in the United States and Switzerland. The U.S. based trial will take place under Stemedica's existing IND for the itMSCs. Swissmedic has found Stemedica's itMSCs acceptable for clinical trials from Phase I to Phase III.

About Stemedica Cell Technologies, Inc.

Stemedica Cell Technologies, Inc. (http://www.stemedica.com) is a specialty bio-pharmaceutical company committed to the manufacturing and development of best-in-class allogeneic adult stem cells and stem cell factors for use by approved research institutions and hospitals for pre-clinical and clinical (human) trials. The company is a government licensed manufacturer of clinical grade stem cells and is approved by the FDA for its clinical trials for ischemic stroke.

Stemedica is currently developing regulatory pathways for a number of medical indications using adult allogeneic stem cells. The Company is headquartered in San Diego, California.

For more information regarding Stemedica Cell Technologies, Inc.

contact Dave McGuigan at: Email - dmcguigan (at) stemedica.com.

Phone - (858) 658-0910 SOURCE Stemedica -0- 04/03/2012 /Web Site: http://www.stemedica.com CO: Stemedica; American College of Cardiology (ACC) ST: California Illinois IN: MTC BIO PHA HEA SU: TRI TDS PRN -- PH81237 -- 0000 04/03/2012 07:00:00 EDT http://www.prnewswire.c

Source URL (retrieved on *04/24/2014 - 4:01am*):
http://www.mdtmag.com/news/2012/04/stemedica-ischemic-tolerant-stem-cells-produce-significant-improvement-cardiac-function-after-heart-attack