**CardioCell Reports Positive Results From the First Phase IIa Clinical Trial Using IV Administration of Stem Cells for Chronic Heart Failure Indications**

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ROME, Aug. 28, 2016 /PRNewswire/ -- EUROPEAN SOCIETY OF CARDIOLOGY CONGRESS 2016 -- Study sponsor [CardioCell LLC](http://www.stemcardiocell.com/), a global biotechnology company that uses allogeneic stem cells for cardiovascular indications, announces data from its[Phase IIa clinical trial](https://clinicaltrials.gov/ct2/show/NCT02123706) "Safety and Efficacy of Intravenous Infusion of Ischemia-Tolerant Allogeneic Mesenchymal Stem Cells in Patients With Non-ischemic Cardiomyopathy" at the European Society of Cardiology (ESC) Congress. [Dr. Javed Butler](http://stemcardiocell.com/about-us/scientific-advisory-board/) – one of the study's protocol designers, as well as Chief of the Cardiology Division and Co-Director of the Heart Institute at Stony Brook University – presents a "Hot Line" Late-Breaking Science Session illustrating statistically significant improvement in 6-minute walk test, quality-of-life scores as assessed by Kansas City Cardiomyopathy Questionnaire (KCCQ) and favorable immune modulatory benefits. This represents the first clinical trial to study the effects of intravenous (IV) administration of ischemia-tolerant mesenchymal stem cells (itMSCs) in patients with chronic heart failure (HF).

"The study's premise was that the stem cell benefits may be related to their paracrine properties," says Dr. Javed Butler, Chief of the Cardiology Division and Co-Director of the Heart Institute at Stony Brook University. "We hypothesized that these benefits should also be retained with IV administration, and, theoretically, enhanced in HF patients who do not have any evidence of myocardial scarring. The results support that IV administration is a safe and viable strategy that has the potential to offer significant health benefits."

**Results Validate Safety and Potential Benefits of IV itMSC Administration**The study protocol tests safety and capacity of CardioCell's itMSCs to exert beneficial effects via IV administration. The methodology demonstrates that the systemic effects of intravenously delivered itMSCs can be measured and is associated with improved patient outcomes. Results show that an IV injection strategy is safe and well-tolerated. There are no major differences in any of the safety endpoints, including clinical events like all-cause mortality, all-cause hospitalization and adverse events, and there are no alterations in pulmonary function, liver function or arrhythmias. In addition, IV itMSC injections exhibit improvements in several clinical-efficacy endpoint measurements, including statistically significant improvement in 6-minute walk test (P=0.02); KCCQ Clinical Summary score (P=0.02) and trend to improvement in KCCQ Functional Status score (P=0.06). The study also demonstrates that intravenously administered itMSCs suppress inflammation, which is noteworthy because inflammation is believed to importantly contribute to HF progression. There was a statistically significant reduction in natural killer (NK) cells, the magnitude of which correlated with the magnitude of improvement in left ventricular ejection fraction (LVEF). Overall, there was no difference in cardiac structure and function. In an exploratory data analysis before the 90-day crossover, there was a statistically significant improvement in the left ventricular end systolic and diastolic volumes in the itMSC-treated groups, whereas this was not seen in the placebo-treated group.

**IV itMSC Administration Opens New Possibilities for Future Stem Cell Therapies**It was previously assumed that large amounts of stem cells must be delivered directly to the myocardium to improve patient outcomes. However, this delivery mechanism – either via catheter or by surgery – is not practical for such chronic conditions as HF, where multiple treatments may be needed. The results of this study suggest that IV itMSC administration could potentially provide a more practical alternative that offers health benefits.

"It is exciting to be part of the first IV stem cell administration study that showed a significant functional improvement for HF patients," says [Dr. Mihai Gheorghiade](http://stemcardiocell.com/about-us/scientific-advisory-board/), a protocol co-designer of this study and Director of Experimental Therapeutics at the Center for Cardiovascular Innovation at Northwestern University Feinberg School of Medicine, Co-chair of CardioCell's Heart Failure Advisory Board and Member of CardioCell's Scientific Advisory Board. "Importantly, itMSCs improved well-being of the patients that have already been on evidence-based HF therapy. This is very innovative and marks a new beginning in HF management, especially in light of negative results of many drug-intervention trials."

**Clinical Trial Offers Implications for Further Study**This study indicates that IV itMSC administration may lead to improvement in patient well-being and exerts associated anti-inflammatory effects. Current data suggests that paracrine signaling is mostly responsible for these signs of improvements, which suggests an IV delivery method is viable. Further, IV administration is more practical than local administration.

"Based on these promising clinical-trial findings, CardioCell is excited to be developing larger studies based on IV delivery of our itMSCs for heart failure indications, including both non-ischemic and ischemic cardiomyopathy," says [Sergey Sikora](http://stemcardiocell.com/about-us/leadership/), CEO of CardioCell and co-author of the study. "We are very encouraged by the degree of statistically significant improvement in patient health status, and we look forward to exploring whether multiple IV treatments will lead to further improvement, including cardiac function."

**About the Phase IIa Clinical Trial**The single-blind, placebo-controlled, crossover study – conducted at Emory University, Northwestern University, Stony Brook University and the University of Pennsylvania – delivered itMSCs via IV infusion to 22 enrolled patients with non-ischemic cardiomyopathy and LVEF ≤40%. The study randomized patients into a treatment group and a control group with a 1:1 randomization scheme. CardioCell's treatment and the placebo were administered intravenously. Progress was tracked at the baseline, at 90 days and at 180 days and was measured by the KCCQ, 6-minute walk, NYHA and cardiac MRI. At 90 days after the first injection, the control group received CardioCell's treatment, and the original treatment group received the placebo solution. At Duke University's cardiac imaging core laboratory, the MRI images were analyzed by Dr. Raymond Kim, founder and co-director of the Duke Cardiovascular Magnetic Resonance Center. Study authors include Javed Butler M.D., MPH, MBA;Stephen E. Epstein M.D.; Stephen J. Greene M.D.; Arshed A. Quyyumi M.D.; Sergey Sikora Ph.D.; Raymond J. Kim M.D., Ph.D.;Allen S. Anderson M.D.; Jane E. Wilcox M.D.; Nikolai I. Tankovich M.D.; Michael J. Lipinski M.D.; Kenneth B. Margulies M.D.; Robert T. Cole M.D.; Hal A. Skopicki M.D., Ph.D.; and Mihai Gheorghiade M.D.

**About itMSCs**Only CardioCell's chronic HF therapies feature itMSCs, which are exclusively licensed from CardioCell's parent company Stemedica. Unlike MSCs grown under normoxic conditions, Stemedica's bone-marrow-derived, allogeneic itMSCs are grown under chronic hypoxic conditions. *In vivo* experiments demonstrate cells that are exposed to hypoxic conditions show greater homing and engraftment than cells grown under normoxic conditions. Compared to MSCs manufactured under normal oxygen condition, itMSCs secrete higher levels of growth factors and other important proteins associated with neoangiogenesis and healing.

**About CardioCell LLC**Founded in San Diego, California, in 2013, CardioCell LLC is a global biotechnology company that explores therapeutic applications of unique, patented, ischemia-tolerant mesenchymal stem cells manufactured under cGMP conditions. CardioCell is a subsidiary of Stemedica Cell Technologies Inc., a global biotechnology company that manufactures adult allogeneic stem cells. The company's technology is based on more than 30 years of research and clinical experience conducted by scientists and physicians in the United States, Europe and the former Soviet Union. CardioCell therapies offer a unique, proprietary technology based on the expansion of cells in constant hypoxia. The company has an exclusive, worldwide license from Stemedica to explore therapeutic indications for unmet cardiovascular needs, such as acute myocardial infarction, chronic heart failure and peripheral artery disease. For more information, visit [www.stemcardiocell.com](http://www.stemcardiocell.com/).

**About Stemedica Cell Technologies Inc.**Stemedica Cell Technologies Inc. is a global biopharmaceutical company that manufactures best-in-class allogeneic adult stem cells and stem cell factors. The company is a government licensed manufacturer of cGMP, clinical-grade stem cells currently used in US-based clinical trials for acute myocardial infarction, chronic heart failure, cutaneous photoaging, ischemic stroke, Alzheimer's disease and traumatic brain injury. Stemedica's products are also used on a worldwide basis by research institutions and hospitals for pre-clinical and clinical (human) trials. Stemedica is currently developing additional clinical trials for other medical indications using adult, allogeneic stems cell under the auspices of the FDA and other international regulatory institutions. The company is headquartered in San Diego, California, and can be found online at [www.stemedica.com](http://www.stemedica.com/).

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