Hemostemix's 4th Heart Study Published in Stem Cell Research & Therapy Confirms Breakthrough Treatment for Heart Disease

written by Raj Shah | October 30, 2023

October 30, 2023 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB: HMTXF) (FSE: 2VF0) is pleased to announce that *Stem Cell Research & Therapy* published the Company's seventh peer reviewed study of ACP-01 – the third peer reviewed study of ACP-01 as a treatment for heart disease (ischemic and non-ischemic dilated cardiomyopathy), which demonstrates ACP-01 regenerates and improves cardiac function by up to 24.1% at 12 months in ischemic cardiomyopathy, and regenerates and improves cardiac function in non-ischemic cardiomyopathy patients by up to 47.1% at 12 months (dLVEF%/iLVEF%).

Cardiomyopathy is chronic disease of heart muscle due to an acquired or hereditary condition. Ischemic cardiomyopathy is the most common form, resulting from inadequate blood flow to the heart, and affecting 2.5 million persons in the USA, with a mortality of 200,000 annually. Non-ischemic dilated cardiomyopathy – due to autoimmune, infectious, infiltrative or familial (genetic) causes – results in dilation and ineffectiveness of the heart wall, with a prevalence of approximately 400,000 persons in the U.S.A., annual mortality of 10 -50%, and is a major cause for cardiac transplantation in children.

Stem cell transplantation is an emerging therapy for severe

cardiomyopathy. Angiogenic cell precursors (ACP-01) are autologous cells (obtained from the patient in a simple blood draw), lineage-specific (programmed to form blood vessels), with strong potential to effectively engraft, and support tissue survival and regeneration.

This study, published in *Stem Cell Research and Therapy*, is an IRB approved, peer reviewed retrospective analysis of 53 adult patients who underwent endovascular implantation of ACP-01 through a catheter for treatment of ischemic cardiomyopathy and non-ischemic dilated cardiomyopathy . The study was not randomized. Cardiac function was assessed by measurement of the left ventricular ejection fraction (LVEF) – the percentage of heart volume pumped out with each heart beat. A normal LVEF is 52-72% in men, 54%-74% in women.

Four months after implantation of ACP-01, those patients with ischemic cardiomyopathy (n = 41) improved by 4.7% (p < 0.004), and by 12 months the LVEF had increased from an initial 29.9 % to 38.2% (p < 0.004). The increase (dLVEF%/iLVEF%) represents an increase in cardiac function of 24.1% at 12 months.

Improvements were more striking in the non-ischemic dilated cardiomyopathy subgroup (n = 8) in whom LVEF increased by 7.5% at 4 months (p < 0.017) and 12.2% at 12 months, from an initial 25.9% to 38.1% (p < 0.003). The increase of LVEF in non-ischemic cardiomyopathy (dLVEF%/ iLVEF%) represents an increase in cardiac function of 47.1 % at 12 months.

The improvement was most marked in the patients with the most severe cardiomyopathy (LVEF < 20%), in whom there is a high risk of sudden death. In this group, the LVEF increased from 14.6% before treatment to 28.4 % at 12 months.

Complications included one death from an unrecognized silent MI one month before treatment, 2 respiratory infections and 2

patients requiring cardioversion. There were no complications attributed to the ACP-01.

This study was not prospective and randomized. However, in the context of 2 previous studies of cardiomyopathy patients who underwent implantation of ACP-01 on a compassionate use basis, the significant results of this study provides a compelling impetus to proceed with a Phase 2 randomised, prospective trial of ACP-01 for treatment of ischemic and non-ischemic dilated cardiomyopthy.

Published Abstract:
Methods: This IRB approved outcome analysis reports upon 74 consecutive patients who failed medical management for severe cardiomyopathy, and were selected to undergo transcatheter intramyocardial or intracoronary implantation of ACP-01. Serious adverse events (SAEs) were reported. Cell analysis was conducted for each treatment. The left ventricular ejection fraction (LVEF) was measured by multi-gated acquisition scan (MUGA) or echocardiogram at 4 (+/- 1.9) months and 12 (+/-5.5) months. Patients reported quality of life statements at 6 months (+/- 5.6 months).
Results: Fifty-four of 74 patients met requirements for inclusion (48 males , 5females; age 68.1 +/- 11.3 years).

The mean treatment cell number of 57 × 10^6 ACP-01 included 7.7 × 10^6 CD34 + cells, and 21 × 10^6 CD31 + cells with 97.6% viability. SAEs included one death (previously unrecognized silent MI), ventricular tachycardia (n = 2) requiring cardioversion, and respiratory infection (n = 2). LVEF in the ischemic subgroup (n = 41) improved by 4.7% (+/- 9.7) from pre-procedure to the first follow-up (4 months +/-1.9 months) (p < 0.004) and by 7.2% +/- 10.9 at final follow-up (n = 25) at average 12 months (p < 0.004). The non-ischemic dilated cardiomyopathy subgroup (n = 8) improved by 7.5% +/- 6.0 at the first follow-up (p < 0.017) and

by 12.2% +/- 6.4 at final follow-up ($p < 0.003$, $n = 6$). Overall improvement in LVEF from pre-procedure to post-procedure was significant (Fisher's exact test $p < 0.004$). LVEF improvement was most marked in the patients with the most severe cardiomyopathy (LVEF < 20%) improving from a mean 14.6% +/-3.4% pre-procedurally to 28.4% +/- 8% at final follow-up. Quality of life statements reflected improvement in 33/50 (66%), no change in 14/50 (28%), and worsening in 3/50 (6%).
Conclusion: Transcatheter implantation of ACP-01 for cardiomyopathy is safe, and improves LVEF in the setting of ischemic and non-ischemic cardiomyopathy. The results warrant further investigation in a prospective, blinded, and controlled clinical study.

"I want to thank the studies authors, including Jane R. Schubart, Amirhossein Zare , Roberto M. Fernandez-de-Castro, Hector Rosario Figueroa, Ina Sarel, Kelly Tuchman, Kaitlyn Esposito, Fraser C. Henderson Sr and Ernst von Schwarz," stated Thomas Smeenk, CEO. "This is our third peer reviewed study of heart disease (41, 106 and 53 heart patients, respectively). Completed by three independent teams, each study confirms ACP-01 is a breakthrough treatment for ischemic and non ischemic cardiomyopathy."

Dr. Fraser Henderson Sr, Hemostemix CMO, commented: "This peer reviewed study, though not prospective or randomized, provides clear data to suggest that transcatheter implantation of ACP-01 results in a significant improvement in cardiac function, especially in those most severely debilitated with very low left ventricular ejection fractions, and in those with non-ischemic dilated cardiomyopathy."

"The results of these three studies significantly derisk a phase II randomized clinical trial," stated Thomas Smeenk. "With it we have attracted and assembled some of the most accomplished stem

cell scientists, transplant surgeons and cardiologists at the McGill University Health Center, to complete this study. That will enable Hemostemix to make ACP available in the near future to the large number of patients suffering with cardiomyopathy," Smeenk said.

ABOUT HEMOSTEMIX

Hemostemix is an autologous stem cell therapy company, founded in 2003. A winner of the World Economic Forum Technology Pioneer Award, the Company has developed, patented, and is scaling a patient's blood-based stem cell therapeutics platform that includes angiogenic cell precursors, neuronal cell precursor and cardiomyocyte cell precursors. For more information, please visit **www.hemostemix.com.**

For a copy of the publication:
https://link.springer.com/content/pdf/10.1186/s13287-023-03539-6.pdf

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*of ischemic cardiomyopathy and related results, the retrospective study of ischemic and dilated cardiomyopathy, and the commercialization of ACP-01 via the sale of compassionate treatments approved by regulators. There can be no assurance that such forward-looking information will prove to be accurate. Actual results and future events could differ materially from those anticipated in such forward-looking information. This forward-looking information reflects Hemostemix's current beliefs and is based on information currently available to Hemostemix and on assumptions Hemostemix believes are reasonable. These assumptions include, but are not limited to: the underlying value of Hemostemix and its Common Shares; the successful resolution of the litigation that Hemostemix is pursuing or defending (the "**Litigation**"); the results of ACP-01 research, trials, studies and analyses, including the analysis being equivalent to or better than previous research, trials or studies; the receipt of all required regulatory approvals for research, trials or studies; the level of activity, market acceptance and market trends in the healthcare sector; the economy generally; consumer interest in Hemostemix's services and products; competition and Hemostemix's competitive advantages; and Hemostemix obtaining satisfactory financing to fund Hemostemix's operations including any research, trials or studies, and any Litigation. Forward-looking information is Subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of Hemostemix to be materially different from those expressed or implied by such forward-looking information. Such risks and other factors may include, but are not limited to: the ability of Hemostemix to complete clinical trials, complete a satisfactory analyses and file the results of such analyses to gain regulatory approval of a phase II or phase III clinical trial of ACP-01; potential litigation Hemostemix may face; general business, economic, competitive,*

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