Hemostemix Announces Phase II Results Plus New Heart Study Demonstrating Statistically Significant Improvement in Ejection Fraction at 4 and 12 Months after ACP-01 Heart Injections

written by Raj Shah | August 30, 2022

August 30, 2022 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB: HMTXF) (FSE: 2VF0) ("Hemostemix" or the "Company") is pleased to announce the results of its Phase II Clinical Trial and the results of a new retrospective study of patients that underwent a trans-catheter, intramyocardial injection of angiogenic cell precursors (ACP-01) as a treatment for heart failure (ischemic and non-ischemic dilated cardiomyopathy).

The 2021 American Heart Association estimated the prevalence of heart failure (HF) in the United States to be 6 million; within 5-years of hospitalization, the death rate amongst this population is approximately 50%. ACP-01 in its capacity to replace damaged cells, secrete growth factors, stimulate angiogenesis and exert an anti-inflammatory effect to minimize scarring, have emerged as a therapeutic option. Hemostemix has just completed an IRB approved, retrospective, outcomes study to analyse the effect of ACP-01 implants on cardiac function in patients with severe heart failure (New York Heart association Grades 3 and 4). Cardiac function was measured in terms of ejection fraction of the left ventricle (LVEF %; normal range

≥55%).

At first follow-up (average 4 months) after ACP-01 cell implantation, for all types of heart failure, the LVEF was increased by 4.6% (from 28.6% to 33.2%), representing a statistically significant improvement (p = 0.0011). On final follow-up (average 12 months after cell implantation) for all patients, the LVEF% had improved by 7.69%, which was statistically significant (p=0.003).

When analyzing ischemic heart failure alone (n=41), LVEF increased from 29.9% before implantation, to 34.5%, and to 38.2% at final follow-up, for an overall improvement of 8.37%, which was statistically significant (p= 0.003). There was greater improvement in the non-ischemic dilated cardiomyopathy patients (n=8), who improved from 25.94% before treatment to 40.29% at final follow-up, for an overall improvement of 14.35% (p=0. 002).

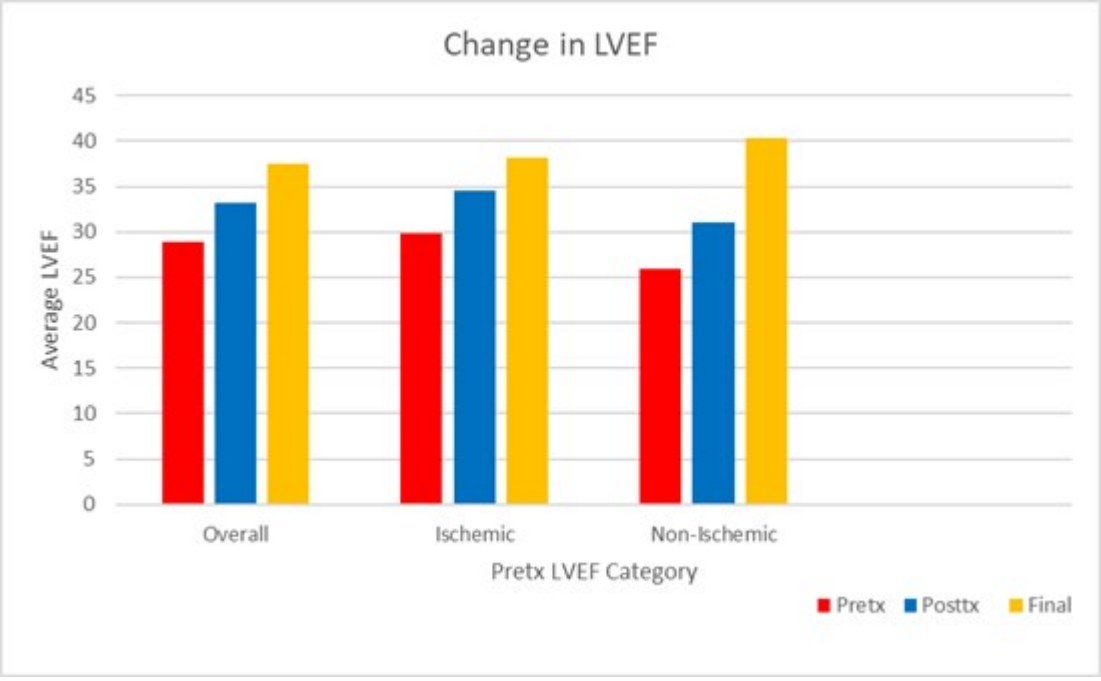

Figure 1

To view an enhanced version of Figure 1, please visit:

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To determine whether the observed improvements after ACP-01 implantation occurred at different levels of cardiomyopathy severity, the patients were divided into quartiles of pre-procedural LVEF%:

(i) those with extremely severe cardiomyopathy, pre-procedural LVEF% <20%;
(ii) those with severe pre-procedural LVEF% 20-29%;
(iii) those with moderately severe cardiomyopathy pre-procedural LVEF% 30-39%
(iv) those termed “heart failure with mid-range EF”, with pre-procedural LVEF% 40-50% (per American College of Cardiology/American Heart Association/European Society of Cardiology)

Overall, upward mobility from one quartile to the next quartile was significant (p=.0007) for first follow up, and more significant (p=0.0002) for final follow up. Three of the four groups moved up into the next category of LVEF function. The greatest improvement of LVEF% was generated in patients with extremely severe cardiomyopathy (LVEF%<20%).

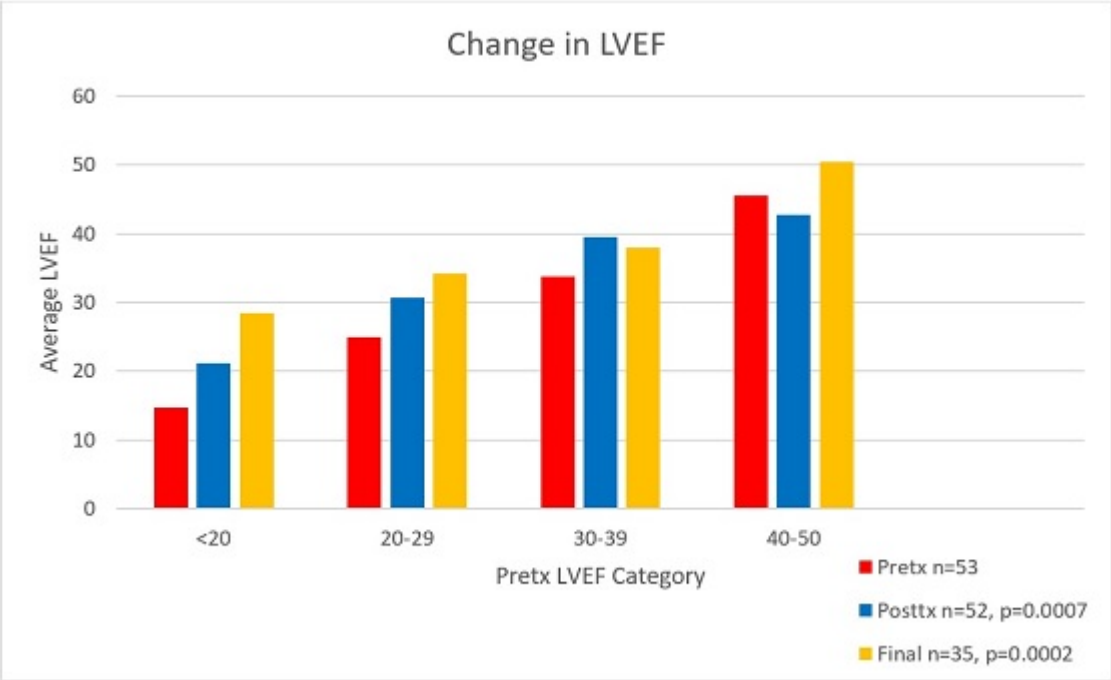

Figure 2

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Quality of life statements were used also to assess response to treatment. Patients receiving ACP-01 implantation reported “improvement of quality of life” in 66% of cases, no overall change in 28% of cases, and worsened quality of life in 6% of cases. Although not statistically significant, 94% of cases were the same or improved following ACP-01 treatment, a contradistinction to the deterioration of quality of life exhibited by the general population of patients with heart failure.

The study’s conclusion is that trans-catheter intramyocardial injection of angiogenic precursor cells (ACP-01) as a treatment for heart failure is feasible and safe. The results are statistically significant and merit randomized, double-blind, placebo-controlled trials to confirm the benefit of this type of cell transplantation.

The calculated LVEF%, derived from MUGA scan, echocardiogram or SPECT was normally distributed, fulfilling the assumption for parametric testing, and treated as continuous variables, expressed as probability density functions. The paired t test compared mean preoperative and postoperative LVEF%. A *p* value of < 0.05 was considered statistically significant.

Phase II Critical Limb Ischemia Trial Results

Hemostemix is seeking regulatory approval to complete a Phase III clinical trial of ACP-01 as a treatment of critical limb ischemia. The trial results demonstrate a trend toward a reduction in amputations, as only 6.52% (3 of 41) ACP-01 patients required amputation, as compared to (9.52% 2 of 21) placebo patients.

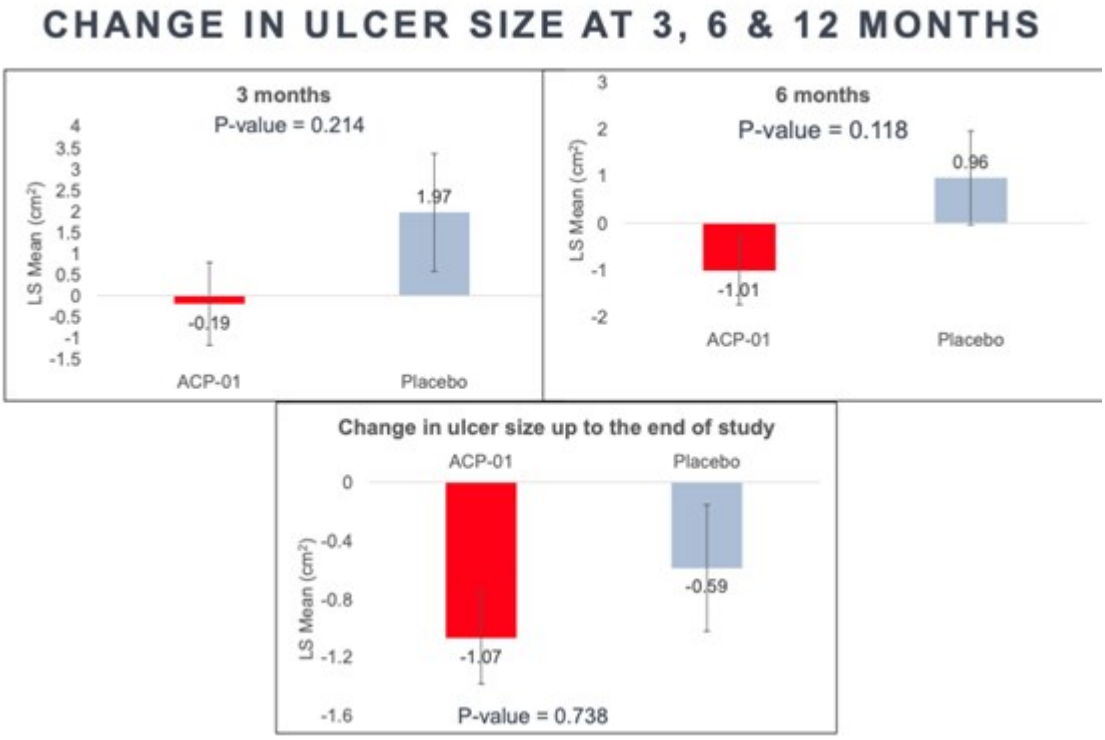

Figure 3

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The trial demonstrated that ACP-01 treated patients, as compared to placebo treated patients:

1. trend toward improvements in ulcer healing at 3 months
2. trend toward ulcer healing at 6 months
3. trend toward ulcer healing at the end of study at 12 months

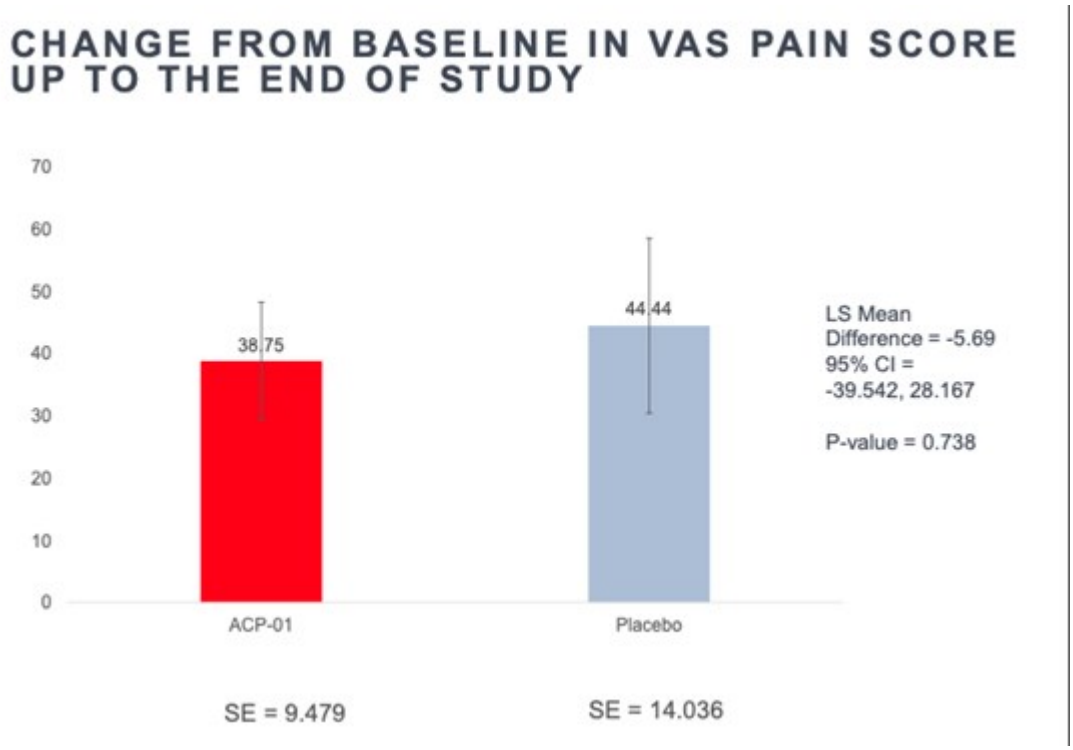

Figure 4

To view an enhanced version of Figure 4, please visit: https://images.newsfilecorp.com/files/5065/135348_02b6afe174792b9b_010full.jpg

4. and, trend toward a reduction in pain associated with critical limb ischemia at 12 months, the end of the study.

As originally designed, the clinical trial power analysis required 95 subjects to achieve a statistically significant result. The previous management team, however, truncated the trial to 65 subjects, reducing to 25% the power for the analysis

of the study’s primary endpoint.

The clinical trial data was generated from patients treated at 17 participating sites across North America. Of 107 patients screened for the clinical trial, 68 were randomized to receive either ACP-01 (n=47) or placebo (n=21). Of the patients treated with ACP-01, 27 completed the study, and 20 withdrew. Of those treated with placebo, 19 completed the study and 2 withdrew. The data was entered into a database hosted by Medrio and the company completed verification of 71% of data points using source documents held at each site. Patient follow-up ranged from 1 day to 401 days since treatment. The median time to event was 241 days.

“Our team rescued the phase II clinical trial, completed an IRB approved retrospective heart study, rescued the company, and saved our shareholders equity. Trans-catheter, intra-myocardial implantation of ACP-01 was demonstrated to be safe and statistically efficacious in both ischemic cardiomyopathy and non-ischemic dilated cardiomyopathy. ACP-01 is also safe as a treatment of critical limb ischemia with positive trends toward wound healing, cessation of pain, and saving limbs from amputation. Proving the efficacy of ACP-01 in prospective, blinded, randomized clinical trial, to gain regulatory approval is next. I want to thank our team who delivered, and I want to thank our shareholders for their continued support as we restart and scale production, generate revenue from licensing and compassionate treatments, and move forward with a phase II clinical trial of heart disease financed, ideally, through a partnership,” stated Thomas Smeenk, CEO.

ABOUT HEMOSTEMIX

Hemostemix is a publicly traded 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. Seven studies including 260 ACP-01 recipients define its safety and efficacy profile as a treatment for Critical Limb Ischemia (43 Subjects), Angina (17 Subjects), and Dilated and Ischemic Cardiomyopathy (200 Subjects). The Company owns 91 patents across five patent families. For more information, please visit **www.hemostemix.com.**

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Forward-Looking Information*: This news release contains "forward-looking information" within the meaning of applicable Canadian securities legislation. All statements, other than statements of historical fact, included herein are forward-looking information. In particular, this news release contains forward-looking information in relation to: the lead product ACP-01, the Phase II Clinical Trial results, the retrospective study, and the commercialization of ACP-01. 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 its current CLI clinical trial, complete a satisfactory analyses and file the results of such analyses to gain regulatory approval of a phase III clinical trial of ACP-01 as a treatment of Critical Limb Ischemia; potential litigation Hemostemis mayface; general business, economic, competitive, political and social uncertainties; general capital market conditions and market prices for securities; delay or failure to receive board or regulatory approvals; the actual results of future operations including the actual results of future research, trials or studies; competition; changes in legislation affecting Hemostemix; the timing and availability of external financing on acceptable terms; long-term capital requirements and future developments in Hemostemix's markets and the markets in which it expects to compete; lack of qualified, skilled labour or loss of key individuals; and risks related to the COVID-19 pandemic*

including various recommendations, orders and measures of governmental authorities to try to limit the pandemic, including travel restrictions, border closures, non-essential business closures service disruptions, quarantines, self-isolations, shelters-in-place and social distancing, disruptions to markets, disruptions to economic activity and financings, disruptions to supply chains and sales channels, and a deterioration of general economic conditions including a possible national or global recession or depression;the potential impact that the COVID-19 pandemic may have on Hemostemix which may include a decreased demand for the services that Hemostemix offers; and a deterioration of financial markets that could limit Hemostemix's ability to obtain external financing. A description of additional risk factors that may cause actual results to differ materially from forward-looking information can be found in Hemostemix's disclosure documents on the SEDAR website at www.sedar.com. Although Hemostemix has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. Readers are cautioned that the foregoing list of factors is not exhaustive. Readers are further cautioned not to place undue reliance on forward-looking information as there can be no assurance that the plans, intentions or expectations upon which they are placed will occur. Forward-looking information contained in this news release is expressly qualified by this cautionary statement. The forward-looking information contained in this news release represents the expectations of Hemostemix as of the date of this news release and, accordingly, it is Subject to change after such date. However, Hemostemix expressly disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as expressly

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