Hemostemix Announces A Clarification

written by Raj Shah | September 1, 2022

August 31, 2022 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB: HMTXF) (FSE: 2VF0) ("Hemostemix" or the "Company") received numerous enquiries about the press release of August 30, 2022. This press release details the results in a table format and clarifies a misprint.

Table 1 is a summary of the 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 first column defines the Patient Category; the second column defines the left ventricle ejection fraction before treatment; the third column defines the left ventricle ejection fraction after treatment; the fourth column defines the left ventricle ejection fraction increase (after LVEF% minus before LVEF%); the fifth column defines the percent increase in left ventricle ejection fraction (after LVEF divided by before LVEF); the sixth column defines the p-value; the seventh column describes remarks.

Patient Category	Before LVEF%	After LVEF%	LVEF% Increase	Percent Increase	P-value	Remark
All Patients at 4 Months	28.6	33.2	4.6	16.08%	p=0.0011	Statistically Significant
All Patients at 12 Months	28.6	36.29	7.69	26.88%	p=0.003	Statistically Significant

Ischemic Heart Failure at 4 Months	29.9	34.5	4.6	15.38%	p=0.003	Statistically Significant
Ischemic Heart Failure at 12 Months	29.9	38.2	8.37	27.75%	p=0.003	Statistically Significant
Non Ischemic Heart Failure at 12 Months	25.94	40.29	14.35	55.31%	p=0.002	Statistically Significant

Outcomes:

1. The percent increase of all patients at an average of 4 months after treatment was 16.08%, p= 0.0011, statistically significant.
2. The percent increase of all patients at an average of 12 months after treatment was 26.88%, p=0.003, statistically significant.
3. The percent increase of the ischemic heart failure patients at an average of four months after treatment was 15.38%, p=0.003, statistically significant.
4. The percent increase of the ischemic heart failure patients at an average of 12 months after treatment was 27.75%, p=0.003, statistically significant.
5. The percent increase of the non-ischemic heart failure patients at an average of 12 months after treatment was 55.31%, p=0.002, statistically significant.

Table 2 clarifies the treatment and placebo cohorts of the Phase II critical limb ischemia clinical trial.

Category	Statistic	ACP-01	Placebo	Total
Subjects randomized	n	47	21	68
Subjects randomized but were not treated	n (%)	1 (2.1)	0	1 (1.5)
Subject treated	n (%)	46 (97.9)	21 (100)	67 (98.5)
Subjects who completed the study	n (%)	27 (57.4)	19 (90.5)	46 (67.6)
Withdrawal from the study	n (%)	20 (42.6)	2 (9.5)	22 (32.4)

46 Subjects were treated with ACP and 21 Subjects were treated with a Placebo. 27 ACP-01 Subjects and 19 Placebo Subjects completed the study. 20 ACP-01 Subjects and 2 Placebo Subjects withdrew from the study and had no amputations at time of withdrawl. The ACP-01 amputation rate was misprinted as 3 of 41. It should have printed as 3 of 27 (11.1%). The placebo amputation rate was misprinted as 2 of 21. It should have been printed as 2 of 19 (10.5%).

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

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.

ACP-01 is safe as a treatment of critical limb ischemia. The results of a previous randomized clinical trial were published in Cytotherapy. After 2 years, 2 patients in the control group died and 6 of 8 limbs were lost to amputation. In the ACP treated group, there were no deaths and 7 of 10 limbs were saved from amputation. Based on the unblinded current results and understandings generated from this phase 2 trial design, and based on the two previous published studies, Management is of the opinion that ACP-01 is worthy of an additional properly designed, prospective, blinded, randomized clinical trial, to prove ACP is efficacious as a treatment of critical limb ischemia.

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**.

For further information, please contact: Thomas Smeenk, President, CEO & Co-Founder
EM: **tsmeenk@hemostemix.com** PH: 905-580-4170

***Venture Exchange) accepts responsibility for the adequacy or accuracy of this release**.*

***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 required by applicable securities law.