Hemostemix Announces Updated Phase II Randomized Clinical Trial Results Published by the Journal of Biomedical Research and Environmental Sciences

written by Raj Shah | February 6, 2024
February 6, 2024 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB: HMTXF) (FSE: 2VF0) ("Hemostemix" or the "Company") is pleased to announce the Journal of Biomedical Research and Environmental Sciences published the Company's Phase II randomized clinical trial results today.

The publication highlights the results of no option critical limb ischemia patients who started the clinical trial with an ulcer, comparing wound healing, amputation, and mortality between the patients treated with ACP-01 and patients treated with a placebo, and stated the following:

- 67 patients with no option Critical limb ischemia were allocated to treatment with ACP-01 (46/67) or placebo (21/67).
- From this data, only patients who presented with wound ulcers before administration of ACP-01 were reviewed (21 treatment, 8 placebo).
- Ulcer size in the treated group decreased from a mean of 1.46 cm2 to 0.48 mm2 ($p = 0.01$) by 3 months. There was no significant decrease in the size of the ulcers of the placebo group ($p < 0.54$).
- At one year there were no complications related to

treatment.

- The treatment group had one amputation (4.8%) and one death (4.8%).
- The placebo group had 2 amputations (25%) and 1 death (12.5%).

“In evaluating the subgroup of patients who presented with ulcerous wounds, there was a significant decrease in ulcer size at 3 months, lower amputation rate at 12 months, and a lower mortality rate at 12 months in the ACP-01 treatment group. Moreover, the 1-year death rate in the patients treated with ACP-01 for CLI (4.8%) was substantially less than the death rate reported in the literature of 15%-20% within 6 months of a CLI diagnosis . Similarly, the amputation rate of 4.8% in this treatment subgrouop compares favorably with the literature, the latter variably reporting amputation rates of 10%-40% per year.,” stated Dr. Fraser Henderson, CMO.

“I want to thank the authors for their scientific contributions, and bringing this clinical data to fruition. The growing body of evidence in eight peer reviewed publications covering 318 subjects suggests that ACP-01 is safe and efficacious in the treatment of various forms of ischemia,” stated Thomas Smeenk, CEO. “We will have additional news of the production of ACP-01 for revenue and clinical trials in the near future, as we are selling ACP-01 as treatment for CLI under exemption,” 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.

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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 publication of its Phase II randomized clinical trial results of its lead product ACP-01, the sales of ACP-01 as an exempt compassionate treatment, the Trademark Know Your Health! and related results, including 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 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 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.