Hemostemix Announces Soft Lock of Database as Source Document Verification Completed

written by Raj Shah | December 9, 2021

December 9, 2021 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB :HMTXF) (FSE: 2VFO) ("**Hemostemix**" or the "**Company**") is pleased to announce the source document verification process has been completed and the Company has soft locked the HS 12-01 database. Next, each of the principal investigators will sign off the source documentation of the subjects they followed. Following the sign off by all principal investigators, the HS 12-01 database will be locked.

The database includes a total of 65 subjects who were randomized on a 2:1 basis to receive ACP-01 or a placebo, respectively. The Company is seeking the return of all of its intellectual property and assets from Aspire Health Sciences, LLC, including the randomization key(s) required to complete the statistical analyses of the trial.

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 developed and is commercializing its lead product ACP-01 for the treatment of CLI, PAD, Angina, Ischemic Cardiomyopathy, Dilated Cardiomyopathy and other conditions of ischemia. ACP-01 has been used to treat over 300 patients, and it is the subject of a randomized, placebo-controlled, double blind trial of its safety and efficacy in patients with advanced critical limb ischemia who have exhausted all other options to save their limb from

amputation.

On October 21, 2019, the Company announced the results from its Phase II CLI trial abstract presentation entitled “Autologous Stem Cell Treatment for CLI Patients with No Revascularization Options: An Update of the Hemostemix ACP-01 Trial With 4.5 Year Follow-up” which noted healing of ulcers and resolution of ischemic rest pain occurred in 83% of patients, with outcomes maintained for up to 4.5 years.

The Company owns 91 patents across five patent families titled: Regulating Stem Cells, In Vitro Techniques for use with Stem Cells, Production from Blood of Cells of Neural Lineage, and Automated Cell Therapy. 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 results of the clinical trial and 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 as well as management's expectations of anticipated results; Hemostemix's general and administrative costs remaining constant; 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 the 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 the results of such analyses and future clinical trials; litigation and potential litigation that Hemostemix may face; 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.