Hemostemix Announces the Protocol First Contract and Warrant Repricing Approval

written by Raj Shah | February 11, 2021

February 11, 2021 (Source) – Hemostemix Inc. ("Hemostemix" or the "Company") (TSXV: HEM; OTC: HMTXF) is pleased to announce it has contracted Protocol First to provide it with source document verification services. Protocol First's P1 Source Upload solution, which runs alongside any EDC system, allows site coordinators to upload un-redacted source data at the click of a button. The CRA/monitor can remote monitor the data, mark it as reviewed, issue queries to the site, and create reports for management, all within an FDA approved solution.

"Protocol First will enable us to complete clinical trial site remote monitoring and source document verification by the end of March" stated Thomas Smeenk, CEO.

"Hemostemix needed a regulatory solution that could be deployed rapidly and provide immediate operational relief to the difficult task of source document verification. We are very happy to provide such a solution and help Hemostemix in this critical process " said Hugh P. Levaux, Ph.D., Founder and CEO for Protocol First.

A total 65 subjects who were enrolled in the trial, randomized 2:1 to receive ACP-01 or a placebo, will have completed the last follow-up appointments by March 31, 2021. The Company will provide additional information once the trial data has been analyzed.

Warrant Amendments

The Company announces the TSX Venture Exchange ("TSX-V") has granted approval to amend the exercise price and expiration date of outstanding warrants (the "**Warrants**") previously issued in connection with non-brokered private placements which closed on March 5, 2020 and March 25, 2020 (the "**Original Private Placements**").

Subject to the accelerator provisions and restrictions applicable to insiders described below, the Warrants of the Company that were scheduled to expire on March 5, 2021 and March 25, 2021 are repriced to $0.55 each and the expiry date extended to March 5, 2023 and March 25, 2023. In accordance with TSX-V policies, the Warrants are amended to include an acceleration clause whereunder the exercise period of Warrants will be reduced to thirty (30) days, if, for any ten consecutive trading days during the unexpired term of the Warrants, the closing price of the Company's listed shares achieves or exceeds the price of 120% of the applicable exercise price ($0.66). The 30-day expiry period commences on the day the Company either (i) disseminates a press release or (ii) sends a written notice to the holders of the Warrants advising of the commencement of the exercise period.

A total of 13,618,522 Warrants were issued to subscribers under the Original Private Placements, including 5,180,000 Warrants issued to certain directors and officers (the "**Insiders**") of the Company. In accordance with the polices of the TSX-V, only 1,361,852 Warrants held by the Insiders, representing 10% of the amended Warrants, will be repriced to $0.55. The remainder of the Warrants held by the Insiders (3,818,148) remain exercisable at $1 per share, subject to all amendments described above.

A portion of the Warrants are held by the Insiders considered to be "related parties" of the Company. Therefore, the amendment of Warrants constitutes a "related party transaction" as

contemplated by Multilateral Instrument 61-101 *Protection of Minority Shareholders in Special Transactions*, and TSX-V Policy 5.9 – *Protection of Minority Shareholders in Special Transactions*. However, the exemptions from formal valuation and minority approval requirements provided for by these guidelines can be relied upon as the fair market value of the Warrants does not exceeds 25% of the market capitalization of the Company. A material change report in respect of this related party transaction will be filed by the Company.

The Company believes that the repricing of the Warrants is reasonable and necessary in the context of the market, as it increases the likelihood that the Company will be financed through the exercise of the Warrants.

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 500 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.

ABOUT PROTOCOL FIRST

Protocol First, Inc., founded in 2015 and headquartered in Salt Lake City, UT, develops next-generation technology solutions for complex clinical trials in the Life Sciences industry. In addition to its flagship Protocol First suite of cloud-based solutions (eProtocol, Source Upload and EDC), Protocol First has launched Clinical Pipe, the industry's first connector app that offers system-agnostic EHR-to-EDC interoperability. The application supports major EHR and EDC systems including Epic, Cerner, Allscripts and Athena, as well as Medidata Rave, Oracle InForm, and its own P1 platform. For additional information visit www.protocolfirst.com.

For further information, please contact:

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Neither the TSX Venture Exchange nor its Regulation Service Provider (as that term is defined under the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this news 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 clinical trial 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 analysis, including the midpoint 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 futility analysis and the results of such 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 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.