Hemostemix to Combine ACP-01 with Dr. James Shapiro's Islet Cells to Treat Type 1 Diabetes

written by Raj Shah | January 12, 2022

January 11, 2022 (Source) – Hemostemix Inc. (TSXV: HEM) (OTCQB: HMTXF) (FSE: 2VFO) ("**Hemostemix**" or the "**Company**") is pleased to announce it has signed a contract with Dr. James Shapiro, University of Alberta, Edmonton and will complete a transfer ACP-01 to Dr. Shapiro's laboratory. The combination of ACP-01, an autologous angiogenic cell precursor that has demonstrated improvement of angiogenesis in the heart and limbs of individuals who suffer from ischemia, and cell transplants from human islets or stem cells, hold huge promise in the treatment of diabetes. Following technology transfer, the team will create a new product by combining the two formulations, beginning with human islets. Thereafter, the team will complete preclinical studies to demonstrate the product's characteristics in vivo, with a plan to move forward with first-in-human testing.

Professor James Shapiro led the clinical team with the "Edmonton Protocol" islet transplant success, and was lead author of the 2000 New England Journal of Medicine ("NEJM") study. He was the principal investigator of an international trial that replicated the Edmonton protocol study success, which was published in the NEJM in 2006. As principal investigator on several international islet transplant trial grants, Dr. Shapiro has brought in more than $85 million in grant and philanthropic support through the U of A for work on islet transplantation. He has been the recipient of multiple awards, including the Hunterian Medal from the Royal College of Surgeons of England, the Gold Medal in Surgery from the Governor General of Canada, Physician of the

Century, and was named one of Nature Biotechnology's most remarkable and influential personalities. He was elected Fellow of the Royal Society of Canada in 2012, and was recently appointed as the Department of Surgery's first Canada Research Council's Chair in Transplantation Surgery and Regenerative Medicine.

Professor Shapiro is a busy clinical hepatobiliary and pancreatic oncology and transplant surgeon, and also maintains an active immunology/transplant research laboratory. His group is actively researching personalized medicine approaches to pancreatic and other hepatobiliary cancers, with generation of human tumor transplantation in immunodeficient mouse models, using a novel pre-vascularized subcutaneous implantation site model.

"I am particularly excited about the potential of ACP-01 to improve early engraftment, survival and function of transplanted human islets and stem cell products, and we are poised to explore this potential," said Dr. Shapiro. "We believe that improving cell survival is key to improving short-term and long-term cell transplant function in our diabetes trials, as we look ahead to future cell therapy treatments that could one day reverse diabetes in the 450 million suffers worldwide," he said.

"In facilitating islet cell survival and mitigating local inflammation and autoimmunity, angiogenic cell precursor (ACP) technology will help to surmount two major obstacles to more widespread adoption of islet cell transplantation for treatment of type 1 diabetes," said Dr. Fraser Henderson, CMO. "In addition, we anticipate salutary effects of ACP upon microvasculature in general and renal function in particular," he said.

"This is the first of many such new developments Hemostemix will

introduce to the market in 2022. In part, this demonstrates the hidden value of Hemostemix as a stem cell platform technology company," said 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 developed and has published seven peer reviewed articles about the safety and efficacy of its lead product ACP-01 for the treatment of CLI, PAD, Angina, Ischemic Cardiomyopathy and Dilated Cardiomyopathy. ACP-01 has been used to treat over 300 patients. ACP-01 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 commercialization of ACP-01 in combination with other therapeutics. 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.