



Hemostemix Announces US FDA Clinical Trial Approval

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CALGARY, Alberta, April 19, 2018 -- Hemostemix Inc. ("**Hemostemix**" or the "**Company**") (TSX VENTURE:HEM), a clinical-stage, autologous cell-therapy company, is pleased to announce that the United States Food and Drug Administration ("FDA") has raised no objections to the Company's Investigational New Drug ("IND") application. This allows the Company to expand its Phase II clinical trial for critical limb ischemia ("CLI") to enroll patients at clinical sites across the United States in addition to Canada, where the Company has already received Health Canada approval. This is a key milestone in the Company's international Phase II double-blind, randomized, placebo-controlled clinical trial.

The ongoing Phase II clinical trial investigates the safety and efficacy of the Company's lead product, ACP-01. The Company's patented process results in producing specific stem cells that have the ability to support the generation of new blood vessels to combat the life-threatening complications of CLI. The stem cells are raised and expanded from the patient's blood and then re-injected into the diseased tissue. The results of the current clinical trial will determine whether the curative effects seen in Phase I trials of ACP-01 will be equally strong in a larger and more varied patient group.

Dr. Ravi Jain, Chief Scientific Officer at Hemostemix, states, "Our Phase II clinical trial approval was previously obtained with Health Canada and now with the US FDA review completed and receiving no objections by the FDA, we can accelerate patient recruitment across Canadian and US trial sites. With the approvals in place, Hemostemix, with its CRO Topstone Research Inc., will be actively onboarding 15-20 clinical trial sites in Canada and the United States over the next 6 months."

"To be expanding the trial across the United States is a significant milestone that will secure the future of ACP-01, as it will expedite the patient intake to meet our trial goals and lay the groundwork for future trials for other indications," commented Kyle Makofka, President and CEO of Hemostemix. "The acceptance by the FDA and Health Canada means that the ACP-01 CLI trial has now met the highest standards of two of the most important regulatory agencies in the world. In addition, the US market is probably the most significant market in the world for CLI."

As previously disclosed, the Company has secured a manufacturing agreement for a state-of-the-art FDA cGMP (Current Good Manufacturing Practices) certified laboratory facility in Orlando, Florida, which will be utilized to manufacture ACP-01 for the Phase II clinical trial. This US facility improves the transportation and logistics for delivering ACP-01 to the clinical trial sites. With the manufacturing agreement in place and FDA approval now received, the Company will focus on securing trial sites and patient enrollment.

About Critical Limb Ischemia (CLI)

CLI is a severe form of peripheral artery disease ("PAD") caused by reduced blood flow to the legs, which can result in a host of complications, including nerve and tissue damage. About half of CLI patients either die or require amputation of the affected limb within one year of diagnosis. Demand for a treatment is on the rise, as CLI predominately affects the growing population aged 50 and older. According to The Sage Group LLC, in the United States alone, approximately 20 million people were affected by PAD in 2015 with that number expected to grow to 30 million by 2030, and approximately 7-8 million people in the United States and Europe suffer from CLI. They estimate medical costs in the United States attributable to CLI amount to approximately US\$25 billion annually.

ABOUT HEMOSTEMIX INC.

Hemostemix is a publicly traded clinical-stage biotechnology company that develops and commercializes innovative blood-derived cell therapies for medical conditions not adequately addressed by current treatments. It is the first clinical-stage biotech company to test a stem-cell therapy in an international, multicenter, Phase II clinical trial for patients with critical limb ischemia, a severe form of peripheral artery disease caused by reduced blood flow to the legs. The Company's proprietary treatment targets a participant's diseased tissue with proprietary cells grown from his or her blood that can support the formation of new blood vessels. The Company's intellectual property portfolio includes over 50 patents issued or pending throughout the world. Hemostemix has a manufacturing contract with Aspire Health Science, LLP ("Aspire") for the production of ACP-01 and for research and development purposes at Aspire's Orlando, Florida facility. Building towards commercialization, Hemostemix has also licensed the use, sale and import of ACP-01 for certain indications to Aspire in certain jurisdictions. The Company is continuing research and development of its lead product, ACP-01 with other applications, including cardiovascular, neurological and vascular indications.

For more information, please visit www.hemostemix.com or email office@hemostemix.com.

Contact:

Kyle Makofka, Chief Executive Officer
Suite 1049, 150 – 9th Avenue S.W.

Calgary, Alberta T2P 3H9
Phone: (403) 340-9207
E-Mail: kmakofka@hemostemix.com

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