



Hemostemix Announces Submission of Orphan Drug Designation Application to the FDA

CALGARY, Alberta, Feb. 04, 2019 -- Hemostemix Inc. (“**Hemostemix**” or the “**Company**”) (TSX VENTURE: HEM; OTCQB: HMTXF) a biotechnology company focused on developing and commercializing innovative blood-derived stem cell therapies for medical conditions not adequately addressed by current treatments, is pleased to announce that it has submitted an application with the US Food and Drug Administration (“**FDA**”) to receive Orphan Drug Designation (“**ODD**”) status for its lead product ACP-01 for the treatment of critical limb ischemia (“**CLI**”).

Kyle Makofka, Hemostemix’s President and CEO commented, “Our Orphan Drug Designation submission is part of our corporate strategy to develop and commercialize ACP-01 and is the first of several other FDA applications the Company is pursuing in 2019. Should the FDA approve the Company’s application, the key benefit to Hemostemix and patients with CLI will be that ACP-01 can be advanced more quickly, allowing the Company to reach another significant milestone, accelerate the development into a Phase III trial and create additional value for shareholders. We are very excited as it will be a major advancement in moving the ACP-01 technology platform forward towards treating CLI and other vascular diseases.”

The Orphan Drug Act (“**ODA**”) provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes “orphan status”).

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Due to small patient numbers, treatment for these rare diseases would not be considered economically feasible without government programs to support their economic viability. Orphan Drug Designation would qualify Hemostemix for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain activities, eligibility for orphan drug grants, and the waiver of certain administrative fees. Similar programs for rare diseases exist in European Union, Japan and other countries. As a result of world-wide support for the development of therapeutic solutions to disease, orphan programs are some of the most successful, time and cost effective programs to develop. The receipt of Orphan Drug Designation status does not change the regulatory requirements or process for obtaining marketing approval.

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 one of the first clinical-stage biotech companies to test a stem-cell therapy in an international, multicenter, Phase II clinical trial for patients with critical limb ischemia (“**CLI**”), a severe form of peripheral artery disease (“**PAD**”) caused by reduced blood flow to the legs. The Phase II trial 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.

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unknown risks, uncertainties, and other factors which may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, but are not limited to, the Company's stage of development, the ability of ACP-01 to qualify for and be granted Orphan Drug Status, future clinical trials and results, long-term capital requirements and future ability to fund operations, future developments in the Company's markets and the markets in which it expects to compete, risks associated with its strategic alliances and the impact of entering new markets on the Company's operations. Each factor should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. Hemostemix expressly disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise.