

Fully funded with strong IP Portfolio, Hemostemix marches forward towards FDA Phase II Clinical Trial Completion

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[Hemostemix Inc.](#) (TSXV: HEM | OTC: HMTXF) continues to move forward with its FDA Phase II clinical trial program of its blood-derived, stem cell therapeutics product (ACP-01) at sites in the United States and Canada.

ACP-01 is being tested as a treatment for medical conditions such as Critical Limb Ischemia (CLI). CLI is a blockage in the arteries, which reduces blood flow and oxygen in the limbs, and can cause conditions such as severe pain in the feet or toes, wounds that won't heal, and if left untreated, could result in the amputation of the affected limb.

Although ACP-01 has been used to treat over 500 patients, currently it is part of a Phase II clinical trial of its safety and efficacy in patients with advanced CLI who have exhausted all other options to save their limb from amputation.

Recently, Hemostemix [announced an update](#) on the ACP-01 clinical trial as the company believes that all follow-up visits of the enrolled trial subjects should be completed by March 31, 2021.

In the clinical trial, 65 subjects were enrolled and randomly 2/3 of the participants received ACP-01 with the other participants receiving a placebo. Once the last follow-up appointment is completed and trial data has been analyzed, the company will provide an update. We expect this information in

late April or early May.

The earlier clinical trials have shown that ACP-01 is safe and effective in the treatment of CLI. The data collected will include treatment success or failure, pain, quality of life, and any adverse effects.

Signs “BREAD” Contract with Canadian Department of Foreign Affairs

In January, Hemostemix also [announced](#) it signed the Building Relationships Entrepreneurs & Dealmakers (BREAD) contract with the Department of Foreign Affairs, Trade and Development.

The BREAD agreement is a Canadian government initiative to assist high-potential, biotech-focused Canadian Small and Medium Enterprises and is designed to accelerate the growth of Canadian biotechnology companies.

The Trade Commissioner Service (TCS) department, within the Department of Foreign Affairs, helps Canadian companies grow into international markets by assessing market potential, finding qualified partners, and resolving problems.

Hemostemix is working with the TCS to source qualified partners to license ACP-01 in foreign markets including the United States, Japan, and South Korea,

Hemostemix – a Platform for Stem Cell Therapies

Hemostemix’s stem cell therapy platform uses the patient’s own blood to harvest the stem cells and the treatment helps to restore circulation in damaged tissues.

Advantages with Hemostemix’s process include the use of blood, which is safer and less invasive than other methods, and since you are using the patient’s own blood, there is no immune

rejection.

ACP-01 has the potential to treat other conditions such as Angina, Ischemic & Dilated Cardiomyopathy, and Peripheral Artery Disease. Currently, Hemostemix is preparing for Phase 2 trials for the treatment of Angina and is seeking joint-venture partners to fund other Phase 2 trials.

The company is also investigating the use of ACP-01 to treat patients hospitalized with COVID-19 that exhibit low oxygen levels and significant inflammation.

Hemostemix has also developed NCP-01 (Neural Cellular Precursor) from blood with the potential to treat neurological conditions such as Alzheimer's, Amyotrophic Lateral Sclerosis ("ALS"), Parkinson's, spinal cord injuries, and stroke-related issues. NCP-01 is currently in the R&D phase and is pre-clinical.

Fully Funded for the Year

In December 2020, Hemostemix [raised \\$2.75 million](#) at \$0.30 per unit that comprised of a share and a warrant priced at \$1.00 for a period of 12 months. Proceeds from the offering are expected to be used to pay for various corporate expenses and to fund the clinical trial costs.

In addition to the cash on hand, Hemostemix has a strong intellectual property (IP) portfolio of 91 patents.

To generate some cash flow, Hemostemix plans to ramp up the revenue side of the business by reinstating its compassionate care revenue stream in the United States.

Final Thoughts

Stem cell treatments have been used for over 30 years to treat people with cancer conditions such as leukemia and lymphoma and

earlier trials of Hemotemix's ACP-01 have shown positive effects in the treatment of CLI.

Factors that increase the risk of CLI include diabetes, high cholesterol levels, high blood pressure, obesity, or smoking. Unfortunately, most of these factors are increasing at an alarming rate. Treatment for these conditions has a billion-dollar market potential.

Currently, Hemostemix has a market cap of only C\$25 million with similar-sized biotech companies focusing on CLI trading much higher.

As a company shifts from FDA Phase II to Phase III clinical trials, we expect the share price and market cap to shift higher to reflect the potential of ACP-01.

Hemostemix steps into the new year with capital and its critical clinical study data in hand

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With a new management team spearheading [Hemostemix Inc.](#) (TSXV: HEM | OTC: HMTXF), the Company started 2021 with its [critical clinical study data](#) in hand. Raising over \$4 million in 2020 and then in December adding an additional \$4 million to the coffers (\$2.75 million at a 50% premium), Hemostemix completed a 1-for-20 share consolidation as it charges into the New Year.

Receiving a copy of its entire clinical trial database relating to the clinical trial for Critical Limb Ischaemia (CLI) using its ACP-01 therapy (Angiogenic Cell Precursors) in [November 2020](#) was a key event for Hemostemix's management team and it garnered real interest from the market.

Hemostemix – Platform for Stem Cell Therapies

Based in Calgary and founded in 2006, Hemostemix is a clinical-stage biotechnology company specializing in blood-derived stem cell therapeutics with its lead product (ACP-01) in Stage 2 clinical trials for the treatment of CLI.

CLI is a disease caused by the narrowing of arteries in the limbs, particularly the legs, hands, and feet, causing chronic pain and soreness. Untreated CLI can sometimes require the amputation of the specific limb.

Stem cell treatments have been used for over 30 years to treat people with cancer conditions such as leukemia and lymphoma.

There are two main types of stem cell transplants: allogeneic and autologous. In an allogeneic stem cell transplant procedure, the patient receives stem cells from a donor. In an autologous stem cell transplant procedure, the patient provides themselves the stem cells for the procedure from various sources, including bone marrow or blood.

Hemostemix's autologous stem cell therapy platform uses the patient's own blood to harvest the stem cells and the treatment helps to restore circulation in the damaged tissues.

Hemostemix has a strong intellectual property (IP) portfolio of [91 patents](#) and has treated more than 500 patients with clinical results showing an improvement in 83% of the patients receiving its ACP-01 stem cell therapy.

Advantages with Hemostemix's process include the use of blood, which is safer and less invasive than extracting bone marrow, and since you are using the patient's own blood, there is no immune rejection.

The clinical trials have shown that ACP-01 is safe and effective in the treatment of CLI. Now that Hemostemix has received the entire clinical trial database, it has entered into a contract with a new Clinical Research Organization (CRO) to complete the midpoint statistical analyses of the efficacy of ACP-01 and expects to publish the results this quarter.

Hemostemix – Not a 1-Trick Pony Company

ACP-01 has the potential to treat other conditions such as Angina, Ischemic & Dilated Cardiomyopathy, and Peripheral Artery Disease (PAD). Currently, Hemostemix is preparing for Phase 2 trials for the treatment of Angina and is seeking joint-venture partners to fund the other Phase 2 trials.

Hemostemix has also developed NCP-01 (Neural Cellular Precursor) from blood with the potential, through building new neuronal lineage cells in a patient, to treat Alzheimer's disease, Amyotrophic Lateral Sclerosis (ALS), Parkinson's disease, spinal cord injuries, and stroke-related issues. NCP-01 is currently in the R&D phase and is pre-clinical.

Market Size

According to the American Heart Association, Cardiovascular disease (CVD) accounted for approximately 1 of every 3 deaths in the United States in 2019.

Factors that increase the risk of CLI include diabetes, high cholesterol levels, high blood pressure, obesity, or smoking, all risk factors also associated with CVD.

Unfortunately, most of these factors are increasing at an alarming rate – a study by the Centers for Disease Control and Prevention (CDC) in the United States, showed the prevalence of diagnosed diabetes has more than doubled from 3.3% in 1995 to 7.40% in 2015, affecting 23.4 million Americans.

According to a market research report released in 2019, the value of just the global CLI treatment market is projected to reach US\$5.39 billion by 2025, up from US\$3.13 billion in 2018, at an annual growth rate of 8%.

Competitive Landscape and Market Cap Comparisons

Even with Hemostemix's recent market surge, its market cap is only C\$32.5 million. Similar-sized biotech companies focusing on CLI trade much higher.

Cynata Therapeutics Limited (ASX: CYP) is an Australian biotechnology company with a Phase 2 clinical-stage trial for its stem cell therapy for CLI using bone marrow and has a market cap of C\$93.6 million.

Pluristem Therapeutics Inc. (NASDAQ: PSTI) is a Phase 3 biopharmaceuticals company, based in Israel, that also has an allogeneic cell therapy for the treatment of CLI using the placenta and has a market cap of C\$231.9 million.

In November 2020, Bristol-Myers Squibb Company (NYSE: BMY) bought MyoKardia, Inc. for US\$13.1 billion. MyoKardia was a clinical-stage biopharmaceutical company that developed therapies for the treatment of cardiovascular diseases and its lead product was a Phase III clinical trial drug used in the treatment of hypertrophic cardiomyopathy (HCM).

As a company shifts from Phase 2 to Phase 3 clinical trials, the market cap often has a step-function shift higher, making it an

ideal time to look at Hemostemix.



[SOURCE:](#)