Revolutionizing the way we treat lack of blood flow diseases by using stem cell therapy

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Every year modern medicine makes new breakthroughs that continue to amaze. Today's company has a breakthrough 'stem cell therapy,' designed to regenerate diseased and damaged tissue, focused on patient's with "ischemic" disease (a lack of blood flow) such as limb ischemia or ischemic heart disease (often leading to a heart attack). The company is a winner of the World Economic Forum Technology Pioneer Award.

Ischemic diseases are a huge global problem. For example, ischemic heart disease (also called coronary disease) affects **around 126 million individuals**, which is **approximately 1.72% of the world's population, annually.** Nine million deaths per annum are caused by ischemic heart disease globally. Limb ischemia, often caused by diabetes, smoking, or age, is another huge area in need of innovative and better treatment.

Today's company is stem cell therapy developer, Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF). Hemostemix's stem cell therapy platform uses the patient's own blood to harvest the stem cells and uses them in a treatment that helps to restore circulation (blood flow) in damaged tissues.

Hemostemix's leading product, 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 (CLI)

who have exhausted all other options to save their limb from amputation.

Hemostemix state on their website:

“Hemostemix’s proprietary platform technology is based on more than 10 years of clinical data demonstrating the ability of our autologous cell product to regenerate diseased and damaged tissue. Our efficient, scalable and cost-effective platform has **the potential to generate therapies for a broad range of ischemic diseases**. ACP-01, our lead clinical stage candidate, is an autologous cell therapy for the treatment of critical limb ischemia. ACP-01 is currently in a Phase 2 clinical trial in Canada and the United States.”

Note: Autologous refers to using the patient’s ‘own’ stem cells.

ACP-01 testing

Twelve patients with critical limb ischemia (CLI) and no interventional options were enrolled (10 male, 2 female, mean age 76 years) in an abstract trial test.

Hemostemix quote the results stating:

“Prior to treatment with ACP–01 or placebo, 3 patients had ischemic rest pain, 8 patients had ulceration, and one patient had gangrene. Post treatment, one patient with unremitting rest pain and toe gangrene required a below knee amputation, and one patient with gangrene of the first to third toes required a forefoot amputation. **Healing of ulcers and resolution of ischemic rest pain occurred in the other 10 (83%) patients.** There were no clinically significant safety issues. Outcomes have been maintained for up to 4.5 years (3.5 years for 2 patients, 3 years for 1 and 1 patient died after ulcer healing secondary to congestive heart failure at 6 months).”

Hemostemix latest development for their leading product ACP-01

Hemostemix is currently working on the source document verification for their Phase II clinical trials for their lead product 'ACP-01' for the treatment of critical limb ischemia (CLI), peripheral artery disease (PAD), angina, ischemic cardiomyopathy, dilated cardiomyopathy and other conditions of ischemia. The document verification completion is expected to be completed by the end of 2021.

Note: Clinical trials follow a typical series from early, small-scale, Phase 1 studies to late-stage, large scale, Phase 3 studies, followed hopefully by FDA approval.

Closing remarks

Hemostemix is revolutionizing the way we treat ischemic disease by using stem cells developed from a patient's own blood. Abstract trials on ACP-01 led to an 83% success rate and the Company is now working towards Phase II trials.

Hemostemix is working towards revolutionizing the way we treat lack of blood flow, ischemic, diseases by using its stem cell therapy and has a market cap of C$11 million,

Further learning

- Hemostemix Announces the Second Stem Cell Recipient Interview: One Week to No Chest Pain
- Hemostemix Announces the First of a Series of 2021 Video Interviews with ACP-01 Recipients: What the Successful Compassionate Treatment of Ischemic Cardiomyopathy Looks Like After 13 Years

Thomas Smeenk with an update on the FDA Phase II clinical trial program of the Hemostemix blood-derived, stem cell therapeutics product (ACP-01)

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In a recent InvestorIntel interview, Peter Clausi speaks with Thomas Smeenk, Co-Founder, President and CEO of Hemostemix Inc. (TSXV: HEM | OTC: HMTXF) about the Phase II Clinical Trial on Hemostemix's ACP-01 which has the potential to treat patients with severe critical limb ischemia.

In this InvestorIntel interview, which may also be viewed on YouTube (click here to subscribe to the InvestorIntel Channel), Thomas went on to say that Hemostemix is in the process of completing the source document verification. With about 60% of source documents verified, Thomas said that they expect the source document verification to be complete within the year.

To watch the full interview, click here

About Hemostemix Inc.

Hemostemix is a publicly traded autologous stem cell therapy company. 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 entitled "Autologous Stem Cell Treatment for CLI Patients with No Revascularization Options: An Update of the Hemostemix ACP-01 Trial With 4.5 Year Followup" 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.

To know more about Hemostemix Inc., click here

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If you have any questions surrounding the content of this interview, please email info@investorintel.com.

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.