Hemostemix posts promising clinical trial results from heart failure and limb ischemia treatment

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Heart failure (HF) is a growing epidemic in the United States, with an estimated 6 million people affected. HF is a debilitating condition that can significantly reduce patient quality of life and, in severe cases, prove fatal. Within five years of hospitalization, the death rate for HF patients ranges from 45% to 60%. Given the high mortality rate and the significant impact on quality of life, there is a great need for effective treatments for HF.

Stem cell therapy has been touted as a revolutionary medical treatment for a variety of conditions for some time. Stem cells have a number of properties, including paracrine and anti-inflammatory effects, that are potentially useful for conditions where conventional medical treatments do not lead to enough optimal patient outcomes.

Acute cardiac progenitor cells (ACP-01) have emerged as a promising therapeutic option for HF. These cells have the ability to replace damaged cells, stimulate new blood vessel growth, and reduce inflammation. One company, in particular, has been working for years to develop and commercialize these cells in new treatments.

Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF) is developing new treatments to treat ischemic (restricted blood flow) diseases. Hemostemix's technology uses a patient's own cells, collected

through a simple blood draw, to treat that patient's disease. Its proprietary technology collects synergetic cell population and manufactures a personalized regenerative therapy that can be administered to a patient within 7 days of the initial cell collection. The efficient, scalable, and cost-effective platform has the potential to generate therapies for a broad range of ischemic diseases.

On August 30th, 2022, Hemostemix announced the results of their retrospective study of heart disease and the phase II clinical trial results of ACP-01 as a treatment for critical limb ischemia.

In the heart disease study, patients received a direct injection into the heart, or a balloon angioplasty-like release of ACP-01 into the heart's vasculature to address either hardening of the arteries (ischemic cardiomyopathy), or thickening of the heart wall (dilated cardiomyopathy).

The study showed that ACP-01 positively affects cardiac function in patients with both types of severe heart failure. The researchers measured cardiac function in terms of the volume of blood the heart pumps with each beat, the ejection fraction of the left ventricle (LVEF%) before and after ACP treatment at an average of 4 and 12 months. It was found that the LVEF% was increased by 16.08% in all patients at first follow-up and by 26.88% on final follow-up. These results suggest that ACP-01 may be a viable treatment option for patients with severe heart failure.

The results of ACP-01 treatment for critical limb ischemia showed that ACP-01 was safe, trended to improve the healing of ulcers at 3, 6, and 12 months, and trended to a reduction in pain at 12 months. In a previous randomized trial of 20 subjects, after 2 years there were no deaths and 7 of 10 limbs

were saved from amputation, compared to the control group where 2 patients died and 6 of 8 limbs were lost to amputation. Hemostemix's press release noted that its previous management team truncated the trial to 65 subjects, which effected the power of the study. The overall encouraging results of these studies showcase the need for further clinical trials of ACP-01.

Thomas Smeenk, CEO of Hemostemix, commented in the press release that the results show ACP-01 is safe and statistically effective as a treatment of heart disease, safe as a treatment of critical limb ischemia, and worthy of additional clinical trials. "Proving the efficacy of ACP-01 in prospective, blinded, randomized clinical trial, to gain regulatory approval is next," he said.

Hemostemix has said that its next move is to go "forward with a phase II clinical trial of heart disease financed, ideally, through a partnership." Clinical trials can be expensive, and it is not uncommon for smaller biotechnology companies to partner with larger companies or pharmaceutical giants to fund their way through different levels of trials to regulatory approval, provided early results are promising. Hemostemix's results could well attract the right kind of attention.

Built on arguably one of the greatest medical breakthroughs

of our time, Hemostemix has ‘your fountain of youth’…

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Stem cell therapy is potentially one of the greatest medical breakthroughs of our time. It is truly amazing that we can use our own bodies’ stem cells to heal certain diseases. The technology is evolving, but today’s company is making great steps forward to bringing stem cell therapy to patients.

Hemostemix Inc. (TSXV: HEM | OTCQB: HMTXF | FSE: 2VFO) is a company that is developing ‘stem cell therapy’ for the treatment of ischemic (lack of blood flow) disease and several other diseases. Some examples include using the patient’s own stem cells to heal ischemic heart disease (causing angina and heart attack), limb ischemia, vascular dementia, ischemic kidney disease, possibly diabetes, and even in some cases chronic pain. 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.

How does it work?

Hemostemix explains how their stem cell therapy works by stating:

“Hemostemix’s technology uses a patient’s own cells to treat that patient’s disease. The cornerstone of this autologous technology is a novel cell population within the blood called the **synergetic cell population** (SCP). The synergetic cell population, which can be collected from a simple blood draw, consists of progenitor and other supporting cells that are being developed for the treatment of ischemic diseases. Hemostemix’s

proprietary technology includes methods for collecting the synergetic cell population and manufacturing (isolation, enrichment and differentiation) a personalized regenerative therapy that can be administered to a patient within 7 days of the initial cell collection."

About Hemostemix and their lead therapy ACP

Hemostemix was founded in 2003 and is a winner of the World Economic Forum Technology Pioneer Award. Hemostemix's pioneering stem cell treatment is called angiogenic cell precursor (ACP), or ACP-01 for the first one.

Hemostemix has published numerous peer reviewed clinical trials regarding the safety and efficacy of ACP-01 for the treatment of limb ischemia, peripheral arterial disease (PAD), angina, and ischemic cardiomyopathy, involving treatment of over 300 patients.

Case studies show that Hemostemix's stem cell therapy (named ACP) is effective

Below are just 3 of many case study results:

For example:

1. The results of the 106 subjects suffering from ischemic cardiomyopathy "[experienced] improved cardiac function (Left Ventricle Ejection Fraction), improved exercise capacity, and improved quality of life…"
2. The results of 41 subjects treated by direct injection of ACP into the heart to treat ischemic and dilated cardiomyopathy: "Overall ejection fraction improved significantly… At a mean of 180 days after injection, NYHA functional class improved significantly…subjects …improving nearly 126 meters in walking capacity in six

minutes."

3. The 83% of subjects treated compassionately for critical limb ischemia who "… had clinically significant improvement of adequate circulation at the distal limb for…complete healing."

Latest news

In the latest news, Hemostemix announced on February 14 that they have trademarked the term "Your Fountain of Youth" for a period of 10 years.

In other news Hemostemix recently announced a partnership with My Next Health. My Next Health Inc. (MNH) is the world's leading patient focused, AI-functional-medicine-based genomic medical analysis company.

Finally, an exciting piece of news from January 2022, when Hemostemix announced that they plan to combine ACP-01 with Dr. James Shapiro's Islet Cells to treat Type 1 Diabetes. The news states: "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."

Note: The global diabetes care drugs market reached US$69.7 billion in 2019. The global market for diabetes care products including drugs and devices is expected to exceed US$111.2 billion by 2027.

Closing remarks

Hemostemix is at an interesting stage of development where they have spent many years proving their science and technology works, with several favorable clinical trial results. The next

stage is the most exciting for investors, when the Company gets to commercialize the technology. Of course, once this starts to gain success the stock price would typically be much higher. Hemostemix states: “91 Patents. More to follow as we scale Manufacturing and R&D.”

The market for stem cell therapy to treat various diseases is potentially huge. Just think of how many people suffer from ischemic and degenerative diseases. There may also be a market to treat diabetes if the latest Dr. Shapiro pre-clinical studies go well. If we can safely grow back healthy cells in our body to repair damaged tissue, then the potential rewards are enormous. Hemostemix gets this, as we can see from their recent trademark name – “Your Fountain of Youth”.

Hemostemix trades on a market cap of C$8 million. Patience is required but there is huge potential for reward if Hemostemix takes off.

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 bio-therapeutics 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: