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.