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

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.

Canada's defense sector and Tekmira lead the way to finding Ebola cure

The Ebola outbreak shows no sign of stopping and 500 new case have been identified since Canada promised to a hundred doses of an experimental vaccine to the World Health Organization (WHO). The doses remain at the National Microbiology Laboratory in Winnipeg. This latest Ebola epidemic started in Guinea in early 2014 and then spread quickly to Liberia and Sierra Leone, threatening Nigeria, Africa's most populous country.

As cynical as it may sound, there is no doubt that the Ebola epidemic has stimulated the biotech sector to work on specialized vaccines. The outbreaks in West Africa will enable private and government research facilities to measure the effectiveness and safety of the vaccines or serums allow for development with international partners and gain an understanding of the risks and side effects as compared to benefits. Moreover, the data collected in the field' will serve as the basis to secure approval by regulatory

authorities and speed up clinical trials; normally, vaccines are tested for years before their use is permitted. The companies with experimental drugs to treat Ebola include Tekmira Pharmaceuticals ('Tekmira', NASDAQ: TKMR), BioCryst Pharma (NASDAQ: BCRX), NewLink Genetics (NASDAQ: NLNK), and Sarepta Therapeutics (NASDAQ: SRPT). Of these Tekmira has the best chance of success thanks to the fact it is working on an actual drug able to fight Ebola even in patients who has already contracted the disease a week. Ebola symptoms tend to show up days after the infection with the virus occurs, so drugs are needed to stop the developing illness.

Shares of Vancouver based Biotechnology Company Tekmira Pharmaceuticals have returned to yearly highs over the month of August. The recent Ebola epidemic was first noted last January but the world did not take notice until a few months later. The recent trading success was prompted by the fact that, given the magnitude of the emergency, American authorities have partially allow its use of as part of the experimental treatments to combat the epidemic. The market is betting that Tekmira has the remedy, soaring close to 50% in August trading, and boosted by the prospect of the use of one of its experimental Ebola treatments may have as much success in 90% of cases. The US Federal Drug Administration (FDA) informed Tekmira that it had decided to speed up the validation process and paved the way for its use to combat the epidemic in Africa.

Tekmira has the advantage of being the only vaccine to be tested on humans (even if only healthy patients participated in the testing) making Tekmira the scientific community's treatment of choice against Ebola for the time being. In August, Tekmira won a USD$ 140 million contract with the United States Department of Defense to further develop the TKM-Ebola treatment. Some analysts have suggested that Tekmira, a small company, may generate more than USD$ 100 million in revenue by 2017 through its Ebola remedy alone. In

perspective, in the first quarter 2014, Tekmira generated USD$ 4.4 million in revenue and a net loss worth more than four times that amount. It should be noted that much of the advancements made by Tekmira and all the other companies searching for a drug to fight Ebola came courtesy of Canada's Department of National Defence, which invested several million dollars into programs aimed at protecting Canada from Ebola and other diseases considered to be security threats.

Defence Research and Development Canada (DRDC) has supported the National Microbiology Laboratory in contributing to the development of Winnipeg, ZMapp and Tekmira. Nevertheless, after having proven to be successful in treating some affected medics, the new vaccine remains complicated to deliver. It must remain stored at very low temperatures to work and shipped accordingly. The priority remains to ensure availability of the vaccines to health care workers – as they risk their lives to save others and are essential – but the problem is that there is a limited supply and producing new ones can take two to three months. Fears of an Ebola epidemic from breaking out domestically has also forced the Canadian Health ministry to maintain 500 to 700 doses of vaccine in the country. In fact there are two potential vaccines or serums against Ebola.

The experimental, Canadian developed, VSV-EBOV vaccine is the one that is expected to be delivered to West Africa even though the equally experimental serum ZMapp has already been used to cure two American aid workers. The San Diego based Mapp Biopharmaceutical (NASDAQ: MAPP) is having difficulty increasing production in time even if it has addressed the emergency situation, noting that it is working with commercial and government entities to meet demand. A Canadian lab only has a dose of ZMapp left while three doses of serum are required to treat a single patient; it takes three or four months to produce a small amount. Zmapp has successfully treated two American workers.

The main difference between VSV-EBOV (vaccine) and ZMapp (serum) is that the vaccine is not produced using a virus from the same family as the rabies virus, vesicular stomatitis, which is transmitted from animals to humans. The serum is plant based and, being a serum, it works after a person has been exposed to the virus. VSV-EBO, as a vaccine it acts ‘preemptively’. Unlike serums vaccines are generally designed to be used to prevent an infection before it occurs. VSV-EBOV, similar to an anti-rabies vaccine, may also have success if used on patients already affected by Ebola, because anti-rabies vaccines have shown to be effective if used quickly – that is they can cause an immune response if they are adopted before the virus ‘wins’. Injected after exposure to virus, the VSV-EBOV proved somewhat effective in animals.