

Corporate Profile:

CardioVascular BioTherapeutics, Inc.



CardioVascular BioTherapeutics, Inc. (OTC/BB: CVBT) is a biopharmaceutical developing surgical and topical formulations of its lead compound, Fibroblast Growth Factor 1 (FGF-1₁₄₁) which has multiple applications for the regenerative treatment of cardiovascular disease. FGF-1₁₄₁ is a human protein manufactured using a proprietary technology that stimulates angiogenesis, vasculogenesis, and neurogenesis.

CVBT is continuing to advance its technical platform through clinical trials to specifically treat impaired blood supply and damaged tissue associated with:

- ✓ Severe Coronary Heart Disease (CHD)
- ✓ Dermal Wounds
- ✓ Peripheral Arterial Disease (PAD)
- ✓ Disc Ischemia
- ✓ Lumbar Ischemia

CLINICAL TRIAL SUMMARY

Clinical Trials:

- **Severe Coronary Heart Disease (CHD):** In March 2006, the Company completed enrollment and treatment of 21 patients at 6 U.S. sites in its Phase I trial for patients with severe coronary heart disease. The 12 month follow-up visits for the last two patients will be completed in March 2007. Final safety data is being collected, and a Phase II protocol is being completed with input from the FDA. To date there have been no reports of significant unexpected adverse effects attributable to the injections.
- **Topical Dermal Wound Healing:** The FDA authorized a Phase I trial for wound healing of dermal ulcers, which began in 2006, and is expected to conclude in 2007. Three patients have been treated as of December 31, 2006 in a two-site FDA authorized Phase I clinical trial for a total of eight patients with diabetic foot ulcers. Based on the outcome of the Phase I trial and discussions with the FDA, the Company plans to begin further clinical trial in 2007.
- **Peripheral Artery Disease:** The FDA has authorized a Phase I clinical trial for Peripheral Artery Disease (PAD). The FDA has authorized the initiation of a Phase I trial for the treatment of PAD, specifically for patients with intermittent claudication. The trial is expected to begin in 2007; 24 patients will be enrolled, each of whom will be given three escalating doses of the drug. Magnetic Resonance Imaging (MRI) will be used to measure increased circulation.

Pre-Clinical Studies:

- **Disc Ischemia:** Investigational study underway with the Orthopedic Education and Research Institute of Southern California to establish non-invasively the correlation of under-perfusion with disc degeneration.
- **Lumbar Ischemia:** Investigational trials currently underway in Russia and Serbia with the Russian Academy of Sciences to treat lumbar ischemia or chronic back pain.

Coronary Heart Disease
15.8 Million Affected

Peripheral Artery Disease
8 Million Affected

Dermal Wounds
20.8 Million Affected

Chronic Back Pain
26 Million Affected

Note: Data is U.S. only

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PRODUCT DEVELOPMENT PIPELINE

Indication/ Project Name	Research	Preclinical	Phase I	Phase II
Severe Coronary Heart Disease (CVBT-141A)	✓	✓	✓	Planned '07
Dermal Wound Healing (CVBT-141B)	✓	✓	In Progress	Planned '07
Peripheral Artery Disease (CVBT-141C)	✓	✓	In Progress	Planned '07
Disc Ischemia (CVBT 141-D)	✓	In Progress		
Lumbar Ischemia (CVBT-141-E)	✓	In Progress		

A LONG HISTORY OF CLINICAL SUCCESS

The first clinical study with a formulation of CVBT-141A was conducted by Dr. Thomas Stegmann from 1995 to 1997 in Fulda, Germany. CVBT-141A was injected directly into the wall of the heart of 20 patients with severe coronary heart disease. These patients also received a coronary bypass procedure (CABG). A control group of 20 patients received CABG alone. The patients treated with CVBT-141A showed a significant increase in localized blood vessel growth at the site of the injection. These vessels persisted when monitored at a three year follow-up examination. The blood vessel growth was determined to be statistically significant over controls at both six months and three years following injection of CVBT-141A (p-value of < 0.005 at each time period).

A second clinical study of 20 patients was performed from 1998 through 1999, where CVBT-141A injection was used as the sole therapy; there was no control group in this study for ethical reasons, as administration of the placebo would have required unnecessary surgery. The results of the second study demonstrated no adverse events from the growth factor injection and no adverse safety effects of the therapy. Notably, 80% of patients showed a significant increase in tests that measure blood flow and 90% of patients had an improvement in their dominant clinical symptom, chest pain. For two patients angina scores remained the same, but during stress exercise tests chest pain was either completely absent or began at much higher levels of exertion.

COMPANY REPRESENTATIVE CONTACTS

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