



For immediate release:

Fibrex Medical Reports Positive Phase II Results for FX06
Fibrin-derived peptide for the treatment of reperfusion injury in Myocardial Infarction

Cambridge MA, USA and Vienna, Austria, 2 September 2008 - Fibrex Medical, a biopharmaceutical company focusing on cardiovascular and inflammatory diseases, today announced positive Phase II results for FX06, a peptide for the treatment of reperfusion injury – the damage to heart muscle that results from remedial treatment following a heart attack. The results will be presented at the ESC Congress today in Munich, Germany.

The Phase II clinical trial of FX06 (F.I.R.E. study) in 234 patients with acute myocardial infarcts was completed in March 2008, with data indicating a statistically significant reduction in myocardial necrosis compared to placebo following intravenous application of FX06 during reperfusion treatment. FX06 is a peptide that binds to vascular endothelial (VE) cadherin, thereby inhibiting tissue inflammation and injury as well as preserving endothelial barrier function. These effects are deemed to be important for the prevention of the paradoxical additional damage to the heart muscle known as reperfusion injury.

“We are delighted that FX06 has demonstrated efficacy in this Phase II trial” stated Dr. Rainer Henning, President and CEO of Fibrex Medical. “FX06 is a first in class product and we have demonstrated that it can provide clinical benefit by preventing reperfusion injury for the huge number of patients who survive heart attacks each year. FX06 can clearly be expected to become an important addition to the armamentarium of the cardiologist in the catheter lab.”

“Re-establishment of blood flow either by catheter-based balloon-intervention (PCI) or by thrombolysis, is necessary and life-saving in the treatment of acute myocardial infarctions, however such interventions can lead to tissue damage due to resulting free radicals and an acute inflammatory response,” said Dan Atar, Professor of Cardiology at the Aker University Hospital, University of Oslo, Norway, who is the Coordinating Investigator for the F.I.R.E. Study. “Based on the F.I.R.E. results, we believe that FX06 can inhibit this inflammatory response and thus prevent reperfusion injury in patients. We predict that FX06 may become a novel treatment for STEMI patients undergoing PCI representing a major advance in acute cardiac care.”

Fibrex is now planning an ambitious development program to bring this promising new product to registration and expect to carry this program out together with a licensing partner. This program will be discussed with regulatory agencies in US and Europe later this year.

About Fibrex Medical Inc.

Fibrex Medical Inc. is a privately held company headquartered in Cambridge, MA, USA with operations in Vienna, Austria. The Company is developing innovative therapeutics for acute and intensive care in cardiovascular and inflammatory conditions based on novel mechanisms of action. Fibrex Medical started operations in 2001, and has raised a €13 M in investments from top tier venture capital investors including Atlas Venture, Global Life Science Ventures, EMBL Ventures and Mulligan Biocapital.

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Notes to editors:

Acute Myocardial Infarction (AMI) and reperfusion injury

Acute Myocardial Infarction (AMI) remains to be the number one cause of death in the developed world with approximately 2.1 million new cases per year in the USA, Western Europe and Japan. Percutaneous coronary intervention to re-establish blood flow has become the standard of care for AMI patients. While rapid reperfusion is essential to preserve myocardium, the sudden exposure of the ischemic area to blood leads to an acute inflammatory reaction causing additional damage. It is now well accepted that this process termed reperfusion injury limits clinical success of the intervention.

About the Phase II (F.I.R.E.) study:

The Phase II clinical trial of FX06 (F.I.R.E. study) randomized 234 patients with acute myocardial infarcts, to FX06 or placebo, with data indicating a statistically significant reduction in myocardial necrosis following intravenous application of 400 mg FX06 at the time of reperfusion. Detailed results are presented at the ESC Congress on 2nd September in Munich, Germany.

Magnetic resonance imaging data showed that at 5 days after the treatment, the necrotic zone of the infarct was significantly reduced by 58% with FX06 and the total zone of the left ventricle affected by the ischemia was reduced by 21% (not statistically significant). This was accompanied by a reduction of markers of muscle damage (troponin I and CK-MB). After 4 months the resulting scar was also reduced to some extent, suggesting that a reduction of reperfusion injury leads to decrease in scar formation. There were signs of clinical efficacy as well, since cardiac related serious events were also lower in FX06 treated patients (21 vs. 29 events).