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Fibrex Medical Completes Enrolment of Phase II Trial of Treatment for Reperfusion Injury in Myocardial Infarction

234 patients randomized for Phase II study of FX06 within 14 months

Boston MA, USA and Vienna, Austria, November 30, 2007 - Fibrex Medical Inc., a biopharmaceutical company focusing on cardiovascular and inflammatory diseases, today announced that its subsidiary Fibrex Medical Research & Development GmbH has completed patient enrolment for a Phase II clinical trial of FX06 to target reperfusion injury – the damage to heart muscle that results from remedial treatment following a heart attack. FX06 acts by preventing the inflammatory response that can occur when blood flow is restored. It is this inflammatory response that results in much of the damage to heart muscle following Acute Myocardial Infarction (AMI). 234 patients for the study were randomized within 14 months.

The trial, which is referred to as the F.I.R.E (FX06 in Ischemia and REperfusion injury) study, is a double-blind placebo-controlled study involving 33 leading centres of interventional cardiology in eleven European countries. The primary endpoint is myocardial infarct size measured at five to seven days post percutaneous coronary intervention. FX06 has been administered to patients that have just suffered from AMI and the effect on heart muscle preservation during reperfusion has then been assessed using the most advanced imaging technologies, magnetic resonance imaging (CMR) and Tc99m single photon emission tomography (SPECT). FX06, through its potent inhibition of leukocyte transmigration and prevention of vascular leak, is expected to prevent reperfusion injury and reduce infarct size. The F.I.R.E. study aims to clinically demonstrate this activity.

“Completion of this study in such a short period of time is a major achievement,” stated Rainer Henning, President and CEO of Fibrex Medical. “FX06 is a first in class product, generating a lot of excitement in the interventional cardiology community. We thank all of our investigators for their dedication and commitment to this trial and our CRO, IFE Europe GmbH for a great job in organizing the trial. We are now looking forward to obtaining the results of the study which are expected after a four month follow up period in the second quarter of next year.”

“Over the last 20 years, many drugs have been tested for the prevention of reperfusion injury without much clinical success”, said Dan Atar, Professor of Cardiology at Aker University Hospital, University of Oslo, Norway, who is the Coordinating Investigator for the F.I.R.E. Study. “We are very hopeful that FX06 with its unique mechanism of action will advance to become the first effective drug for this indication.”

About Fibrex Medical Inc.

Fibrex Medical Inc. is a privately held company registered in Boston, 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 total of €13 million in capital 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.

How FX06 works

The process that leads to the sudden inflammatory response is caused by a massive influx of leucocyte subtypes responding to the reperfusion. FX06 is a peptide that potently inhibits the binding of fibrin E1 fragment to vascular endothelial (VE) cadherin. The drug has been shown to inhibit extravasation of major leukocyte subtypes by blocking transmigration through the endothelial layer, a bottleneck in the inflammatory cascade. In addition the drug potently prevents vascular leakage and edema formation at the site of injury.