

## BioLineRx Receives Approval to Complete Phase 1/2 Clinical Trials of BL-1040, a Breakthrough Treatment for Acute Myocardial Infarction

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Five out of 30 patients already safely treated. Final results of trial expected in Q3 2009

Jerusalem, ISRAEL, January 12, 2009 - BioLineRx Ltd. (TASE: BLRX), a clinical stage drug development company, today announced that the Independent Safety Monitoring Board (ISMB) for the BL-1040 pilot study authorized the completion of the Phase 1/2 study and enrollment of the additional 25 patients. The ISMB's decision is based on safety assessments of the first 5 patients to complete at least 30 days of follow up following treatment with BL-1040 without noticeable adverse events. BL-1040 is a breakthrough treatment for preventing further heart damage following acute myocardial infarction (MI).

The pilot Phase 1/2 multi-center open label study is designed to assess the safety and preliminary efficacy of BL-1040 in up to 30 patients. The trial is currently taking place in 6 active sites in Germany and Belgium, with 4 additional sites pending. Interim results presenting a 6 months follow-up of the first 5 patients are expected during Q2, 2009, and final results of the pilot Phase 1/2 study are expected in Q3, 2009. BL-1040 is being developed as a Class III medical device utilizing U.S. Food and Drug Administration's pre-marketing approval regulatory pathway. This expedited regulatory pathway should allow marketing of BL-1040 by 2012.

"We are extremely pleased with the progress in the development of BL-1040, and expect that the compound will complete the Phase 1/2 study in Q3 and hope to partner with a global device or drug company following our Q3 results. Business development activities have already begun, and several global biopharmaceutical and device companies are showing significant interest," said Morris C. Laster, MD, CEO of BioLineRx. "BioLineRx anticipates potential initial revenues in 2009 if and when out-license agreements may be secured from the partnering of BL-1040 and/or BL-1020, our Phase 2 small molecule for the treatment of Schizophrenia that will also be available for licensing following final Phase 2b data in Q3 2009. The Company has sufficient capital to fund its activities through the end of 2010, which is 4-5 quarters after achievement of key clinical milestones, allowing ample time to close a partnering deal," added Dr. Laster

## About BL-1040

BL-1040 represents a breakthrough approach to support cardiac tissue damaged as a result of acute MI, improving cardiac function and survival. The novel myocardial implant is a resorbable liquid polymer that is administered via the coronary artery during standard catheterization and flows into the damaged heart muscle. The liquid polymerizes within the infarcted cardiac tissue and forms a protective "scaffold" that enhances the mechanical strength of the heart muscle during recovery and repair, thereby preventing pathological enlargement of the left ventricle after the MI. It is excreted naturally from the body within six weeks after injection, leaving behind a stronger, more stable heart muscle. BL-1040 was in-licensed by BioLineRx from Ben-Gurion University through BGN Technologies in January of 2005. For further information on BL-1040, please visit the BioLineRx website and BL-1040 animation.

## **About Acute Myocardial Infarction**

Acute MI is a leading cause of morbidity and mortality in the Western world. Approximately 1.3 million cases of nonfatal MI are reported each year in the U.S. alone, with an annual incidence rate of approximately 600 cases per 100,000 people. BL-1040's worldwide market potential is estimated at \$4 billion.

## About BioLineRx

BioLineRx, a clinical stage drug development company traded on the Tel Aviv Stock Exchange (TASE: BLRX), is dedicated to building a robust pipeline of promising therapeutics for unmet medical needs. The Company's lead programs include BL-1020 for the treatment of schizophrenia, currently in Phase 2b trials; and BL-1040 for the treatment of damaged heart tissue post-myocardial infarction, currently in a Phase 1/2 study. Additional products under development include compounds for the treatment of cancer and CNS, cardiovascular, metabolic, infectious and autoimmune diseases.

BioLineRx advances projects from early stage discovery and lead generation to advanced clinical trials. BioLineRx partners with researchers, universities and biotech companies to further the development of promising compounds. The Company was founded in 2003 by leaders in the Israeli life science arena including Teva Pharmaceuticals Ltd., venture capital firms Giza Venture Capital and Pitango Venture Capital, and Hadasit, the technology transfer company of Hadassah Hospital and the Jerusalem Development Authority. For more information, please visit <a href="https://www.biolinerx.com">www.biolinerx.com</a>.

This press release contains "forward-looking statements" that involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," "hope,", "look forward" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under applicable laws, we do not intend to update or revise any forward-looking statements.

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