



## First Pivotal Trial for BL-1040, Medical Device for Patients Following Acute Myocardial Infarction, Anticipated to Commence in H2 2011

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BioLineRx (TASE:BLRX) announced today that the first pivotal trial for BL-1040\*, a novel medical device intended for patients following acute myocardial infarction (AMI), is anticipated to commence in the second half of 2011.

Ikaria Inc., which acquired the license for continuation of development and commercialization of BL-1040 from BioLineRx in July 2009, is leading BL-1040's clinical development.

The trial aims to evaluate the safety and effectiveness of BL-1040 for prevention of ventricular remodeling and congestive heart failure when administered following AMI. The trial will be a placebo-controlled, double-blind trial including approximately 270 patients. These patients will be treated with BL-1040 following AMI and will then be monitored for six months.

For further details of the clinical trial, see the National Institutes of Health (NIH) website: [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

**Dr. Kinneret Savitsky, BioLineRx CEO**, said: "We are very pleased with the intensive efforts being made by Ikaria to continue development of BL-1040, a unique product for prevention of pathological cardiac remodeling. The trial is the first of two partially overlapping clinical trials to be carried out by Ikaria. They include a large number of patients and aim to examine the safety and efficacy of BL-1040. We have the utmost confidence in the abilities of Ikaria's experienced team to carry out the trial to the highest professional standards. Meanwhile, BioLineRx's team is continuing to move forward with the rest of our projects and search for additional promising projects to add to the Company's pipeline."

\* BL-1040 is being developed by Ikaria as IK-5001

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### About BL-1040 (IK-5001)

BL-1040 is a medical device, injected to patients following acute myocardial infarction, intended for prevention of pathological cardiac remodeling and subsequent congestive heart failure. It is a liquid polymer creating a scaffold within injured cardiac muscle, designed to enhance cardiac mechanical strength during the healing period and prevent pathological ventricular dilation. BL-1040 degrades within several weeks of injection. Pre-clinical studies in various animal models have demonstrated BL-1040's safety and efficacy in preventing cardiac wall thinning and preserving cardiac function.

In addition, BioLineRx has successfully completed a phase I/II clinical trial which examined the safety and feasibility of treating patients with BL-1040 following acute myocardial infarction. An Independent Safety Monitoring Board reviewed the data from the study and concluded that the treatment is safe and clinical development of the device may continue.

In July 2009, BioLineRx signed an out-licensing agreement with Ikaria, which is developing BL-1040 as IK-5001.

### About BioLineRx

BioLineRx Ltd. is a publicly-traded (TASE:BLRX) biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's business model is based on acquiring molecules, mainly from biotechnological incubators and Israeli academic institutions. The next stages, which include feasibility assessment studies and development through pre-clinical and clinical stages, are performed with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium to large pharma companies to continue advanced clinical development (Phases II and III) and commercialization.

BioLineRx's current portfolio consists of three clinical stage candidates (BL-1040, BL-1020 and BL-5010) as well as eight products in various pre-clinical development stages spanning a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases. BioLineRx also operates a unique Early Development Program (EDP) to develop innovative early-stage projects until sufficient data is obtained for entry into the Company's portfolio.

To date BioLineRx has signed two out-licensing agreements. In July 2009, BL-1040, for treatment following acute myocardial infarction, was out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties. BL-1020 (CYP-1020), for schizophrenia treatment, was out-licensed in June 2010 to Cypress Bioscience Inc. for continuation of development and commercialization in North America only, for a total deal value of \$365 million, in addition to sales royalties.

For more information about BioLineRx, please visit [www.biolinerx.com](http://www.biolinerx.com).

*The estimates and judgments with respect to BL-1040 included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates, including clinical trial commencement dates, may not be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.*