



BioLineRx Announces Initiation of CE Mark Registration Trial for BCM (BL-1040), a Novel Medical Device for Prevention of Cardiac Remodeling Following Acute Myocardial Infarction

January 3, 2012 3:29 PM IST

For Hebrew convenience translation please click link below:

[Hebrew version](#)

Jerusalem, January 3, 2011 - BioLineRx (NASDAQ:BLRX; TASE:BLRX), a biopharmaceutical development company, announced today the commencement of the PRESERVATION I clinical trial, a CE Mark registration trial of BCM (BL-1040), a novel medical device intended for the prevention of cardiac remodeling following an acute myocardial infarction (AMI). The trial has commenced in Australia, will be followed in Europe, and is expected to commence in additional countries, including Israel. Ikaria Inc., which acquired the license for continuation of development and commercialization of BL-1040 from BioLineRx in July 2009, is now leading BL-1040's clinical development as Bioabsorbable Cardiac Matrix (BCM), previously named IK-5001.

PRESERVATION stands for A Placebo Controlled, Multicenter, Randomized, Double-Blind Trial to Evaluate the Safety and Effectiveness of IK-5001 for the Prevention of Remodeling of the Ventricle and Congestive Heart Failure After Acute Myocardial Infarction.

PRESERVATION I aims to evaluate the safety and effectiveness of BCM (BL-1040) for prevention of ventricular remodeling and congestive heart failure when administered following AMI. The trial is a placebo-controlled, randomized, double-blind, multi-country and multi-center trial including approximately 300 patients which are expected to be recruited across 45 sites. This includes approximately 50 Australian patients at 11 clinical trial sites. The BCM device will be administered to subjects who had successful percutaneous coronary intervention with stent placement after ST-segment elevation myocardial infarction (STEMI) and they will then be monitored for six months.

Dr. Kinneret Savitsky, CEO of BioLineRx, said, "We are excited to announce the beginning of this pivotal trial for European registration of BL-1040/BCM, a unique product for prevention of pathological cardiac remodeling following AMI. Our strategic partner, Ikaria, who is leading the development of BL-1040/BCM, is making intensive efforts to swiftly develop this breakthrough device and we are confident that their experienced team will carry out the trial to the highest professional standards. We look forward to the results of the PRESERVATION I trial during 2013."

About BL-1040 (BCM)

BL-1040 is a medical device, injected to patients following acute myocardial infarction, intended for prevention of ventricular remodeling and subsequent congestive heart failure. Ventricular remodeling is the structural alteration of the damaged heart muscle that occurs following an acute heart attack. Once this damage occurs, the weakened heart muscle forces the rest of the heart to compensate. Under this extra workload, the heart muscle dilates, the walls of the heart thin, and the heart further remodels, thereby causing another cycle of dilation and overcompensation. The extra workload to the heart causes further structural damage and can lead to congestive heart failure. BL-1040 is a liquid polymer which is delivered in a bolus injection via the coronary artery during catheterization and flows into the damaged heart muscle, 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 and is excreted through the kidneys. Pre-clinical studies in various animal models have demonstrated BL-1040's safety and efficacy in preventing cardiac wall thinning and preserving cardiac function.

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 clinical development of the device may continue.

Ikaria acquired the exclusive worldwide license to develop and commercialize BCM from BioLineRx in 2009.

More information on the PRESERVATION I trial can be found at www.clinicaltrials.gov.

About BioLineRx

BioLineRx Ltd. is a publicly-traded biopharmaceutical development company. It is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of five clinical stage candidates: BL-1020 for schizophrenia has commenced a Phase II/III study; BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, is commencing a pivotal study and has been out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I development and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed Phase I. In addition, BioLineRx has eleven products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase III) and commercialization.

For more information about BioLineRx, please visit 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 and results 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. Any forward-looking statements represent the Company's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

Contacts:

Garth Russell / Todd Fromer
KCSA Strategic Communications
1 212-896-1250 / 1 212-896-1250
grussell@kcsa.com / tfromer@kcsa.com

Tsipi Haitovsky
Public Relations
+972-3-6240871
tsipih@netvision.net.il