



## **BioLineRx Reports Publication in Peer Review Journal of Results from Previous Phase 1/2 Trial for BCM (BL-1040), a Novel Medical Device for Prevention of Cardiac Remodeling Following Acute Myocardial Infarction**

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*- Results of first-in-man study published in Circulation: Cardiovascular Interventions -*

*- BCM (BL-1040) is currently undergoing PRESERVATION I, a CE Mark registration trial conducted by Bellerophon, with study completion anticipated in mid-2015 -*

JERUSALEM--(BUSINESS WIRE)--Oct. 31, 2014-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today publication of the results of a previous Phase 1/2 (pilot) study for IK-5001 (BL-1040), currently named Bioabsorbable Cardiac Matrix (BCM), a novel resorbable polymer solution for the prevention of cardiac remodeling following an acute myocardial infarction (AMI). This first-in-man pilot study, which was completed in 2010, demonstrates that intracoronary deployment of BCM is feasible and well tolerated.

The study, which was now published in the journal [Circulation: Cardiovascular Interventions](#), was conducted by BioLineRx, and was performed at selected sites in Germany and in Belgium. Twenty seven AMI patients were enrolled and treated with BCM within seven days after the infarction. Clinical safety assessment, including coronary angiography, holter monitoring and blood tests, shows that BCM deployment was well tolerated following the coronary injection, and patient evaluation at six months after treatment confirmed the sustained safety profile of the product. In addition, echocardiography six months after treatment showed preservation of left ventricular functional indices in study participants, implying that BCM has potential to help in preventing cardiac remodeling of the left ventricle. This data is limited due to the uncontrolled nature of the study, but is encouraging in its resemblance to results observed in former pre-clinical studies.

BCM, which was out-licensed to Bellerophon in 2009 for further development and commercialization, is in the midst of the PRESERVATION I study, a CE Mark registration trial at over 80 sites worldwide, 16 of which are in the U.S. To date, over 280 patients have been enrolled in the study, which is designed to enroll a total of approximately 300 patients. Enrollment is expected to be completed by the end of this year, with study completion anticipated in mid-2015.

"We are pleased that the results of this Phase 1/2 trial have been published in a highly respected peer journal, since these results were the basis for initiation of the multicenter, randomized and controlled PRESERVATION I CE Mark registration trial to confirm the safety and efficacy of this new approach in high-risk AMI patients," said Dr. Kinneret Savitsky, BioLineRx's CEO. "1.5 million cases of myocardial infarction occur annually in the U.S. alone, many of which result in irreversible pathological cardiac remodeling. Pre-clinical studies show that BL-1040 is efficacious at preventing cardiac remodeling following an acute myocardial infarction. The pre-clinical studies, along with certain encouraging trend data in the Phase 1/2 study, raise the hope that we will be able to help preserve cardiac function for millions of potential patients around the world. We are eagerly awaiting completion of the PRESERVATION I trial being carried out by our partner Bellerophon, which is expected in mid-2015."

### **About BCM (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. BCM 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. BCM degrades within several weeks of injection and is excreted through the kidneys. Pre-clinical studies in various animal models have demonstrated BCM's safety and efficacy in preventing cardiac wall thinning and preserving cardiac function.

BioLineRx successfully completed a Phase 1/2 pilot clinical trial in 2010 which examined the safety and feasibility of treating patients with BCM following acute myocardial infarction.

Bellerophon (f/k/a Ikaria) acquired the exclusive worldwide license to develop and commercialize BCM from BioLineRx in 2009.

### **About BioLineRx**

BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which is in the final stages of a Phase 1/2 study.

For more information on BioLineRx, please visit [www.biolinerx.com](http://www.biolinerx.com) or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

*Various statements in this release concerning BioLineRx's future expectations, including specifically those related to the development and commercialization of BL-1040, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.*

*These statements include words such as “may,” “expects,” “anticipates,” “believes,” and “intends,” and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the “Risk Factors” section of BioLineRx’s most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 17, 2014. In addition, any forward-looking statements represent BioLineRx’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.*



Source: BioLineRx Ltd.

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