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

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- PRESERVATION I trial completion anticipated in mid-2015 -

JERUSALEM--(BUSINESS WIRE)--Jan. 14, 2015-- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that patient enrollment has been completed in Bellerophon's PRESERVATION I pivotal CE Mark registration trial of 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).

"We are very excited with the successful completion of this important milestone by our partner Bellerophon," said Dr. Kinneret Savitsky, BioLineRx's CEO. "1.9 million cases of myocardial infarction occur annually in the U.S. and the European Union, many of which result in irreversible pathological damage to the heart, termed cardiac remodeling. BCM is aimed at minimizing the development of cardiac remodeling and pre-clinical studies, along with encouraging trend data from the previous Phase 1/2 study, raise the hope that we will be able to help preserve cardiac function of potential patients around the world. We are eagerly awaiting completion of the PRESERVATION I trial, which is expected in mid-2015."

"In addition, we are very pleased that our previous dispute with Bellerophon has been resolved, as we disclosed earlier today in a Form 6-K submission," concluded Dr. Savitsky.

The PRESERVATION I CE Mark registration trial is a double-blind, placebo-controlled study aimed at evaluating the safety and effectiveness of BL-1040 in the prevention of ventricular remodeling and congestive heart failure when administered following AMI. Three hundred and three AMI patients were enrolled and treated at almost 90 sites worldwide, 16 of which are in the U.S. The study, which includes a six-month follow-up period, is anticipated to be completed in mid-2015.

About BCM (BL-1040)

BCM (BL-1040) is a medical device, injected in 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 has successfully completed a Phase 1/2 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

For more information on BioLineRx, please visit 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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