BioLineRx Announces Top-Line Results from Bellerophon's PRESERVATION I Clinical Trial for Bioabsorbable Cardiac Matrix (BL-1040)

July 27, 2015

TEL AVIV, Israel--(BUSINESS WIRE)--Jul. 27, 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 its partner, Bellerophon, reported top-line results from its PRESERVATION I clinical trial for Bioabsorbable Cardiac Matrix (BCM). BCM, also known as BioLineRx's BL-1040, is an investigational, implantable medical device being studied for the prevention of heart failure following an acute myocardial infarction (AMI), commonly known as a heart attack.

The 303-patient, randomized, double-blinded, placebo-controlled study showed no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints.

BL-1040 was licensed to Bellerophon, then known as Ikaria, in 2009. Prior to partnering the project, BioLineRx invested slightly over $10 million in the development of BL-1040. To date, BioLineRx has received a total of $17 million for this asset under the license agreement.

"While we share in Bellerophon's disappointment with the BCM results, we believe BioLineRx's true value remains in our ability to advance our deep in-house pipeline of mid-late stage assets, including future programs under our strategic collaboration with Novartis, and in particular, our expanding BL-8040 oncology platform," said Dr. Kinneret Savitsky, CEO of BioLineRx. "We are on track to report top-line data from our Phase 2 clinical study of BL-8040 for treating relapsed/refractory AML in Q4 2015. Results from the dose escalation phase of this study demonstrated potential best-in-class mobilization of cancer cells from the bone marrow, as well as significant induction of cancer cell death. Additionally, we reported positive safety and efficacy results from a Phase 1 study for BL-8040 as a novel stem cell mobilization treatment for transplantation. We expect to meet with the FDA in order to discuss our next steps in the clinical development program for this indication, including the design of a planned follow-up Phase 2 study. We are also in preparations to initiate three additional Phase 2 studies for BL-8040 in consolidation AML, in AML patients with the FLT3-ITD mutation, and for hypoplastic myelodysplastic syndrome and aplastic anemia. We eagerly anticipate reaching several key inflection points for our BL-8040 platform over the next 12 months, which we hope will add significant value for BioLineRx and our shareholders."

Dr. Savitsky continued, "We remain well capitalized to achieve our corporate and clinical goals through 2018. So while today's news is unfortunate, we believe it has minimal impact on our business as a whole and our plans going forward. We look forward to Bellerophon presenting the full study data at the upcoming European Society of Cardiology's annual meeting and to providing the next steps for this program."

About PRESERVATION I

PRESERVATION I evaluated the safety and effectiveness of BCM for the prevention of ventricular remodeling and heart failure when administered to subjects who had successful PCI with stent placement after ST-Elevation Myocardial Infarction (STEMI). In the study, subjects were randomized to receive BCM (active treatment) or saline control (placebo treatment) in a 2:1 ratio, two to five days following the initial PCI.

The primary endpoint for PRESERVATION I was the change in Left Ventricular End Diastolic Volume Index (LVEDVI) at six months compared to baseline. LVEDVI is an anatomical measurement of ventricular remodeling that was measured by 3-D and 2-D echocardiography. The secondary endpoints for PRESERVATION I were the Kansas City Cardiomyopathy Questionnaire (KCCQ) (summary score); six-minute walk test (6MWT); New York Heart Association (NYHA) functional classification (physician reported); time to cardiovascular death, non-fatal heart failure events or cardiovascular hospitalizations adjudicated by a Clinical Events Committee; and time to first re-hospitalization due to any cardiovascular event.

Safety was evaluated based on adjudication of cardiac serious adverse events by an independent Clinical Events Committee (CEC), as well as periodic reviews conducted by an independent Data Monitoring Committee (DMC).

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-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML), and has successfully completed a Phase 1 study in stem cell mobilization; BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study; and BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria).

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 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 23, 2015. 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20150727005497/en/

Source: BioLineRx Ltd.

Tiberend Strategic Advisors, Inc.
Joshua Drumm, Ph.D., +1-212-375-2664
jdrumm@tiberend.com
or
Andrew Mielach, +1-212-375-2694
amielach@tiberend.com
or
BioLineRx Ltd.
Tsipi Haitovsky, +972-3-6240871
Public Relations
tsipihai5@gmail.com