



BioLineRx to Present Positive Safety and Efficacy Clinical Data for Novel Stem Cell Mobilization Treatment at the European Hematology Annual Congress

May 27, 2015

JERUSALEM--(BUSINESS WIRE)--May 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 positive safety and efficacy Phase 1 clinical data of its lead clinical candidate, BL-8040, as a novel approach for mobilization and collection of bone-marrow stem cells from the peripheral blood circulation, will be presented in an oral presentation at the [20th Annual Congress of the European Hematology Association \(EHA\)](#) to be held June 11-14, 2015 in Vienna, Austria. Data to be presented include response rates and additional pharmacodynamic studies done on the collected cells. In addition, positive preclinical data from studies supporting BL-8040's mechanism of action as a treatment for acute myeloid leukemia (AML) will be highlighted in a poster presentation. The molecular and cellular mechanisms by which BL-8040 affects AML cells will be presented.

BL-8040 will be featured in the following sessions:

[\(Abstract # S800\) Monotherapy Treatment with a Single Dose of the CXCR4 Antagonist BL-8040 as a Novel Method for Mobilization of Human HSPC and MSC: Results of a Phase 1 Healthy Volunteers Study](#)

- Presenter: Yaron Pereg, PhD – Project Leader
- Session: Stem Cell Transplantation: Clinical
- Date and Time: Sunday, June 14, 8:00 a.m. – 8:15 a.m. CEST
- Location: Room Lehar 1 + 2

[\(Abstract # P171\) The CXCR4 Antagonist BL-8040 Directly Affects AML Blasts by Inducing their Terminal Differentiation and Blocking Survival Signals](#)

- Presenter: Yaron Pereg, PhD – Project Leader
- Session: Acute Myeloid Leukemia - Biology
- Date and Time: Friday, June 12, 5:15 p.m. – 6:45 p.m. CEST
- Location: Poster area (Hall C)

About BL-8040

BL-8040 is a clinical-stage drug candidate for the treatment of acute myeloid leukemia, as well as other hematological indications. It is a short peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of the disease to other organs or organ parts) and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a Phase 1/2, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, BL-8040, when combined with G-CSF, demonstrated an excellent safety profile at all doses tested and was highly effective in the mobilization of hematopoietic stem cells and white blood cells from the bone marrow to the peripheral blood. Additionally, in a Phase 1 stem cell mobilization study in healthy volunteers, BL-8040 as a single agent was safe and well tolerated at all doses tested and resulted in efficient stem cell mobilization and collection in all study participants. Importantly, the results of this study support the use of BL-8040 as one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care.

BL-8040 also mobilizes cancer cells from the bone marrow and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. Importantly, BL-8040 has also demonstrated a direct anti-cancer effect by inducing apoptosis. Pre-clinical studies show that BL-8040 inhibits the growth of various tumor types including multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small cell lung carcinoma, neuroblastoma and melanoma. BL-8040 significantly and preferentially stimulated apoptotic cell death of malignant cells (multiple myeloma, non-Hodgkin's lymphoma and leukemia). Significant synergistic and/or additive tumor cell killing activity has been observed in-vitro and in-vivo when tumor cells were treated with BL-8040 together with Rituximab, Bortezomib, Imatinib, Cytarabine and the FLT-3 inhibitor AC-220 (in NHL, MM, CML, AML, and AML-FLT3-ITD models, respectively). In addition, the current Phase 2 clinical trial in AML patients has demonstrated robust mobilization and apoptosis of cancer cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

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) and has just completed a Phase 1 study in 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-8040, 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.

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