BioLineRx Completes Dose Escalation Stage of Phase 1 Trial for Novel Stem Cell Mobilization Treatment

January 6, 2015

- Results of Phase 1 trial for BL-8040 expected in Q1 2015 -

- Multiple additional clinical milestones for BL-8040 anticipated in 2015 -

JERUSALEM--(BUSINESS WIRE)--Jan. 6, 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 it has completed the dose escalation stage of a Phase 1 trial for its novel oncology platform, BL-8040, as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation. All healthy volunteers completed the treatment phase and results are expected during the first quarter of 2015. BL-8040 is being developed along multiple tracks for the treatment of hematological malignancies and other hematological indications, with multiple clinical milestones expected in 2015.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, “We are very excited about this latest advancement for our BL-8040 platform. Stem cell mobilization is used increasingly as a method of collecting hematopoietic stem cells for transplantation, forming part of the treatment regimen for certain types of hematological cancers, as well as severe anemia or immune deficiency disorders. Although it is a Phase 1 study, the current trial will provide us with efficacy data regarding the mobilization capacity of one or two injections of BL-8040 as a stand-alone therapy, which could significantly shorten and reduce the cost of treatment, as well as eliminate the painful side effects associated with G-CSF.”

“In parallel, BL-8040 is also undergoing a Phase 2 study for treating relapsed and refractory acute myeloid leukemia patients, the results of which are expected in the second half 2015. The robust mobilization of cells seen in our Phase 2 AML study to date has been very encouraging and will hopefully be reflected in our Phase 1 mobilization study.”

“As recently reported, we also expect to commence clinical trials for three additional indications for BL-8040 during 2015,” concluded Dr. Savitsky.

The Phase 1 study consists of two parts. The first part is a randomized, double-blind, placebo-controlled dose escalation study exploring the safety and tolerability of escalating repeated doses of BL-8040 in healthy volunteers. Secondary objectives include assessment of the efficacy of BL-8040 in mobilizing stem cells as a stand-alone therapy, as well as determining the pharmacodynamic and pharmacokinetic profile of the drug. This part was performed in three cohorts, with eight healthy volunteers in each cohort. Following analysis of the data, the optimal safe and efficacious dose of BL-8040 will be selected to be used as a stand-alone therapy in the second part of the study.

The second part of the study is an open-label study designed to assess BL-8040’s stem cell mobilization capacity, as well as the yield of cells collected by apheresis. Secondary endpoints of the study include evaluation of the viability and biological activity of cells mobilized by BL-8040 and collected by apheresis. This part will be performed in a single cohort of eight healthy volunteers who will receive the selected dose regimen of BL-8040 based on the data from the first part of the study.

About Stem Cell Mobilization

High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, as well as various forms of lymphoma and leukemia. Modern peripheral stem-cell harvesting often replaces the use of traditional surgical bone marrow stem-cell harvesting. In the modern method, stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), often with the addition of a mobilizing agent such as Plerixafor (Mozobil), harvested from the donor’s peripheral blood by apheresis, and infused to the patient after chemotherapy ablation treatment. This treatment is highly effective, the peripheral stem cells are easier to collect, and the treatment allows for a quicker recovery time and fewer complications.

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 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.

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 is efficient, both alone and in combination with the anti-cancer drug Rituximab, in reducing bone marrow metastasis of lymphoma cells and stimulating lymphoma cell death. 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) 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.

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 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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