



BioLineRx Reports Successful Top-Line Safety and Efficacy Results for Novel Stem Cell Mobilization Treatment

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- BL-8040 Phase 1 study met all safety and efficacy endpoints -

- High stem-cell yield supports novel single-day collection procedure -

JERUSALEM--(BUSINESS WIRE)--Mar. 25, 2015-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today successful top-line results from the Phase 1 safety and efficacy study 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. All safety and efficacy endpoints were met, showing that treatment with BL-8040 as a single agent was safe and well tolerated at all doses and resulted in efficient stem cell mobilization and collection in all study participants. Importantly, the results support BL-8040 as one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care.

Robust stem cell mobilization was evident in all treated participants, across the different doses tested, supporting a novel approach to stem cell collection. After a single administration, BL-8040 enabled collection of a yield of stem cells that exceeds the number required to support a transplant in all treated participants, following only one collection procedure. The Company intends to present the full set of study results at the European Hematology Association (EHA) Conference taking place in Vienna in June 2015.

Dr. John DiPersio, Chief of the Division of Oncology at Washington University School of Medicine in St. Louis, stated, "I am very impressed and encouraged by the activity of BL-8040 in promoting stem cell mobilization and collection as a single agent. The robust effect seen in all participants substantially differentiates this compound from the currently approved mobilization regimens, which require four to five days of treatment and one to three full-day apheresis sessions, and can be associated with side effects including bone pain. Therefore, a novel agent with the capacity to rapidly mobilize substantial amounts of stem cells, while providing a shorter and better tolerated drug administration and cell collection regimen, will be of great value both medically and in terms of patient comfort."

"We are very enthusiastic about the study results showing the outstanding activity of BL-8040 in promoting stem cell mobilization. The results exceeded our expectations, and validate BL-8040 as a highly differentiated stand-alone treatment for stem-cell collection. We plan to meet with the FDA as soon as practicable, in order to discuss the results of this study and obtain more clarity on the next steps in the clinical development program for this indication," commented Dr. Kinneret Savitsky, CEO of BioLineRx. "In addition to stem-cell mobilization, our BL-8040 platform is also undergoing a Phase 2 study for treating relapsed and refractory acute myeloid leukemia patients, results of which are expected in the second half of 2015. In addition, as recently reported, we expect to commence clinical trials for three additional indications for BL-8040 in the second quarter of 2015."

The Phase 1 safety and efficacy study consisted of two parts. The first part was a randomized, double-blind, placebo-controlled, dose escalation study exploring the safety and tolerability of escalating repeated doses of BL-8040 in three cohorts of eight healthy volunteers. Based on data from the first part, an optimal safe and efficacious dose of BL-8040 was selected, which was used as a stand-alone therapy in a single cohort of eight healthy volunteers in the second open-label part of the study. This part of the study was designed to assess BL-8040's stem cell mobilization capacity, as well as the yield of cells collected by apheresis. Secondary efficacy endpoints of the study included the pharmacodynamic and pharmacokinetic profile of the drug, as well as an evaluation of the viability and biological activity of cells mobilized by BL-8040 and collected by apheresis.

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, 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.

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.

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.

Source: BioLineRx Ltd.

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