



BioLineRx Doses First Patient for BL-8040's Second Indication as Novel Stem Cell Mobilization Treatment

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Results from Phase 1 trial expected by end of 2014 or early 2015; BL-8040 also in midst of Phase 2 trial for AML, with results expected in early 2015

JERUSALEM--(BUSINESS WIRE)--Sep. 3, 2014-- BioLineRx Ltd. (NASDAQ: BLRX)(TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today dosing of the first patient in a Phase 1 trial for a second indication of its BL-8040 cancer therapy platform, as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation, where they can be harvested for transplant supporting the treatment of hematological indications.

"Stem cell mobilization is used more and more as a method of collecting hematopoietic stem cells for transplantation, which is used to treat certain types of cancer such as myeloma, leukemia or lymphoma, as well as for the treatment of severe anemia or immune deficiency disorders. Traditionally, these cells were harvested from the bone marrow using a surgical procedure, which involves general anesthesia. Current treatment regimens involve daily injections for 4-6 days of G-CSF, with or without the addition of a mobilizing agent such as Plerixafor (Mozobil). BL-8040 given as a single injection was previously shown in a Phase 1/2 study in multiple myeloma patients to be highly effective in mobilizing stem cells in combination with G-CSF injections. 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," explained Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "In addition, BL-8040 is currently in the midst of the dose-escalation part of a Phase 2 trial for the treatment of acute myeloid leukemia, which is being conducted at several world-leading cancer research centers in the US and Israel, with results expected in early 2015. We are very excited at this point to continue the clinical development of an additional indication in our BL-8040 cancer therapy platform, and we look forward to providing updates on these important clinical milestones over the next several months," concluded Dr. Savitsky.

The stem cell mobilization Phase 1 study consists of two parts. Part 1 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 pharmacokinetic profile of the drug. This part will be performed in up to 4 cohorts, with 8 healthy volunteers in each cohort. Part 1 of the study will serve to select the optimal safe and efficacious dose of BL-8040 to be used as a stand-alone therapy in Part 2 of the study.

Part 2 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 8 healthy volunteers who will receive the selected dose regimen of BL-8040 based on the data from Part 1.

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 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 method of treatment enables easier collection of peripheral stem cells, as well as 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. BL-8040 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 (cell death). 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.

BL-8040 also mobilizes stem cells from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. 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 combination with G-CSF in the mobilization of hematopoietic stem cells and white blood cells from the bone marrow to the peripheral blood. 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; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) and has commenced a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which is in the final stages of a Phase 1/2 study.

For more information on BioLineRx, please visit www.bioplinrx.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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