



BioLineRx Announces Regulatory Submission for Novel Stem Cell Mobilization Treatment

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Phase 1 Trial of BL-8040 expected to begin in Q2 2014; top-line results expected in H2 2014 BL-8040 is also in Phase 2 for AML; top-line results expected in H2 2014

JERUSALEM, Jan. 13, 2014 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that it has filed the necessary regulatory submissions to commence a Phase 1 trial for BL-8040, a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation. The regulatory submissions were filed with the Hadassah Medical Center Institutional Review Board (IRB), and the study is expected to commence during the second quarter of 2014.

(Logo: <http://photos.prnewswire.com/pmh/20130730/630769>)

The Phase 1 study will be divided into 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 monitoring 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 leukapheresis. Secondary endpoints of the study include evaluation of the viability and biological activity of cells mobilized by BL-8040 and collected by leukapheresis. 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.

"Increasingly, stem cell mobilization is being used as a method of collecting stem cells, either for autologous use or for donation, instead of the surgical procedure of bone marrow harvesting. The current procedure involves daily injections of G-CSF for 4-6 days, a procedure that is costly, and moreover, not effective in up to 20% of multiple myeloma patients. Therefore, we were very enthusiastic about the results of BL-8040's Phase 1/2 study in multiple myeloma patients, recently published in the peer review journal *Clinical Cancer Research*, which showed that a single injection of BL-8040 is highly effective in mobilizing stem cells in combination with G-CSF," explained Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "This trial now aims to assess the mobilization efficacy of BL-8040 as a stand-alone therapy, which could shorten and reduce costs of the mobilization protocol significantly. As previously announced, BL-8040 is also currently in the midst of a Phase 2 study for acute myeloid leukemia patients, the results of which are expected in the second half of 2014. Stem cell mobilization is just one example of the additional hematological indications that we intend to investigate for the BL-8040 platform in the future."

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 Stem Cell Mobilization

High-dose chemotherapy followed by autologous stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, non-Hodgkin lymphoma and Hodgkin lymphoma. Stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), harvested from the peripheral blood by apheresis, and re-infused to the patient after chemotherapy. This type of treatment often replaces the use of traditional bone marrow transplantation, because the stem cells are easier to collect and the treatment allows for a quicker recovery time and fewer complications.

In patients that do not sufficiently respond to G-CSF (up to 20% of multiple myeloma patients), treatment is often augmented by Plerixafor, a drug that inhibits CXCR4, a chemokine receptor that is important in hematopoietic stem cell homing to the bone marrow. However, even after the dual treatment, the mobilization of a sufficient number of stem cells remains a difficult objective in a sizeable proportion of the patients.

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 Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in early 2014; BL-8040 for

treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which recently commenced 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 12, 2013. 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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