BioLineRx Presents Positive Safety and Efficacy Results for Novel Stem-Cell Mobilization Treatment at European Hematology Association Conference

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BL-8040's rapid stem-cell mobilization supports stand-alone one-day treatment for stem-cell collection

Graft derived from BL-8040 treatment shows unique cell composition

TEL AVIV, Israel--(BUSINESS WIRE)--Jun. 15, 2015-- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the presentation of positive safety and efficacy results for its lead oncology candidate, BL-8040, as a novel approach for the collection of stem cells from the peripheral blood circulation. Treatment with BL-8040 as a single agent was found safe and well tolerated at all doses, and resulted in efficient stem-cell mobilization and collection in all study participants. Furthermore, the results support BL-8040 as a one-day, single-dose collection regimen, which is a significant improvement compared to the current standard of care. The full Phase 1 data set was presented yesterday in an oral presentation at the 20th Annual Congress of the European Hematology Association (EHA) in Vienna, Austria.

Robust stem-cell mobilization was evident in all treated participants across the different doses tested, leading to a median 9.5-fold increase of stem cells in the peripheral blood following a single BL-8040 treatment. Two to four hours after a single administration, BL-8040 enabled collection of a stem-cell yield exceeding the number of cells required to support a transplant in all treated participants, following only one collection procedure. These results support a novel approach to stem-cell collection for transplantation purposes in patients with hematological malignancies or other indications. Importantly, the collection of CD34+ cells was accompanied by mobilization and collection of colony-forming cells, as well as T, B and NK cells.

The collected human graft was further assessed for its viability and quality *in vitro* and *in vivo*. The cells collected from the subjects treated with BL-8040 showed excellent engraftment in irradiated mice, followed by a rapid reconstitution of normal hematopoiesis.

The Phase 1 clinical trial was performed on healthy volunteers and consisted of two parts. The first part of the study was a randomized, double-blind, placebo-controlled, dose-escalation study in three cohorts of eight participants each, with each participant receiving two consecutive injections of BL-8040. Results show that BL-8040 is safe and well tolerated up to a dose of 1 mg/kg, and that dramatic mobilization of hematopoietic stem and progenitor cells (HSPCs) was observed across all doses tested. The robust mobilization supports the further use of a single injection of BL-8040 for HSPC collection.

In the second part of the Phase 1 study, eight healthy participants received a single injection of BL-8040 at the highest dose of 1 mg/kg, and four hours later underwent a single, standard leukapheresis procedure. Robust and rapid stem-cell mobilization was evident in all treated participants, supporting a novel approach to stem-cell collection. The median level of collected stem cells was higher than 11 x 10^6 cells per kg, and the level of HPSCs in the peripheral blood circulation 24 hours after injection of BL-8040 enabled an additional apheresis on Day 2, if needed. These data support the use of BL-8040 as a single-agent, single-injection, one-day regimen for the collection of stem cells.

"We are very happy to report these outstanding results supporting BL-8040 as an effective one-day monotherapy for collection of sufficient stem cells for hematopoietic cell transplantation. This is a major improvement over currently available procedures, which are lengthier and sometimes require the combination of several agents and multiple time-consuming apheresis sessions. Moreover, we see an improvement in composition of the collected cells, suggesting the potential of a better quality graft that may improve stem cell transplantation outcomes," said Dr. Kinneret Savitsky, CEO of BioLineRx. "We intend to meet with the U.S. Food and Drug Administration (FDA) in order to discuss our next steps in the clinical development program for this indication, including the design of the planned follow-up Phase 2 study. In addition, we are looking forward to reporting top-line results from the on-going Phase 2 study of BL-8040 for treating relapsed and refractory acute myeloid leukemia patients, which we expect in the fourth quarter of 2015. We also look forward to initiating clinical studies for BL-8040 in three additional indications over the next few months, thus expanding and enhancing the potential of our oncology platform."

At the same conference, the Company also presented positive preclinical results for the treatment of acute myeloid leukemia (AML) at a poster session. The results show that BL-8040 rapidly and efficiently induces cell death of AML cells, and demonstrates for the first time that CXCR4 inhibition is associated with induction of terminal differentiation of AML cells.

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. 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 successfully 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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