



BioLineRx Announces Initiation of Phase 2 Trial for BL-8040 as Novel Stem Cell Mobilization Treatment

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Partial results expected by end of 2016

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BioLineRx Ltd. (NASDAQ/TASE:BLRX) announced today the initiation of a Phase 2 trial for BL-8040 as a novel approach for the mobilization and collection of bone marrow stem cells from the peripheral blood circulation.

The Phase 2 open-label study will be conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, and will enroll up to 24 donor/recipient pairs, aged 18-70. The trial is designed to evaluate the ability of BL-8040, as a single agent, to promote stem cell mobilization for allogeneic transplantation. On the donor side, the primary endpoint of the study is the ability of a single injection of BL-8040 to mobilize sufficient amounts of cells for transplantation following up to two leukapheresis collections. On the recipient side, the study aims to evaluate the functionality and engraftment following transplantation of the BL-8040 collected graft.

The study will also evaluate the safety and tolerability of BL-8040 in healthy donors, as well as graft durability, the incidence of grade 2-4 acute graft versus host disease (GvHD), and other recipient related parameters in patients who have undergone transplantation of hematopoietic cells mobilized with BL-8040.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, "We are pleased to be collaborating with the Washington University School of Medicine, whose bone marrow and stem cell transplantation program is one of the largest in the world, in this Phase 2 trial for our lead oncology platform. The trial will assess BL-8040 as a single agent for stem cell mobilization, for the purpose of harvesting hematopoietic stem cells for transplantation. Hematopoietic stem cells are increasingly used as part of the treatment regimen for certain types of hematological cancers, as well as for severe anemia or immune deficiency disorders. We have already completed a successful Phase 1 safety and efficacy study in healthy volunteers, supporting BL-8040 as one-day, single-dose collection regimen for rapidly mobilizing substantial amounts of stem cells. This represents a significant improvement upon the current standard of care. Since there are no approved drugs for stem cell mobilization to support allogeneic transplant, we are looking forward to the partial results expected by the end of 2016 and topline results expected by the end of 2017."

"We continue to expand and enhance the potential of our unique BL-8040 oncology platform, with multiple clinical studies in additional indications, including as a potential combination treatment with immune checkpoint inhibitors. We are also eagerly awaiting the top-line results from BL-8040's Phase 2 trial for the treatment of relapsed and refractory AML patients, which we expect to report by the end of this month," added Dr. Savitsky.

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 is currently in the midst of a Phase 2 study for relapsed/refractory acute myeloid leukemia (AML) and has recently initiated a Phase 2b study as an AML consolidation treatment and a Phase 1/2 study in hMDS and AA. In addition, 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 effectively 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 also 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). 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 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.

About BioLineRx

BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has recently initiated a Phase 2 study in stem cell mobilization; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2 study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For additional information on BioLineRx, please visit the Company's website at <http://www.biolinerx.com>, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).

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 10, 2016. 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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