



## BioLineRx Reports Publication in Peer Review Journal of Positive Phase 1/2 Results in Stem Cell Mobilization for Multiple Myeloma

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**- Results published in Clinical Cancer Research -  
- Additional clinical trial in stem cell mobilization expected to commence in H1 2014 -**

JERUSALEM, Nov. 19, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today the publication of results showing that BL-8040 (formerly known as BKT-140) enables the efficient mobilization of stem cells from the bone marrow into the peripheral blood, thus facilitating autologous stem cell transplantation in multiple myeloma patients. The research was published in the journal, [Clinical Cancer Research](#).

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

High-dose chemotherapy followed by autologous stem cell transplantation has emerged as 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 more traditional use of 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 respond well enough to G-CSF (up to 20% in multiple myeloma), 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 patients.

BL-8040 is a novel, potent and selective inhibitor of the CXCR4 chemokine receptor. The results, obtained in 2011 and currently published in *Clinical Cancer Research*, show that BL-8040 binds with a very high affinity to CXCR4, and more importantly, it dissociates from the receptor in a very slow fashion. As a result, BL-8040 has the unique ability, when compared to other CXCR4 inhibitors, to completely shut down the cell signaling process governing cell trafficking in the bone marrow. This exclusive activity of BL-8040 leads to a strong synergistic effect when combined with G-CSF, resulting in a rapid and robust stem cell mobilization therapy that is differentiated from the current standard of care.

This ability of BL-8040, which was originally demonstrated in animal studies, was confirmed in patients in a phase 1/2 non-randomized, open-label, dose escalation, multi-center study in multiple myeloma patients who underwent stem cell mobilization and collection for autologous stem cell transplantation. Results of the clinical study show that BL-8040 was well tolerated at all concentrations, and that when combined with G-CSF, a single administration of BL-8040 at the highest dose (0.9 mg/kg) resulted in robust mobilization and collection of stem cells, which were then obtained through a single apheresis. Furthermore, all transplanted patients rapidly engrafted. At the highest dose, the median times to neutrophil and platelet recovery were 12 and 14 days, respectively.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, said, "We are very pleased with these promising results in stem cell mobilization, which are the basis for our decision to initiate an additional clinical trial for BL-8040 in this indication. In addition, we remain on track with BL-8040's on-going Phase 2 study for the treatment of relapsed and refractory acute myeloid leukemia patients, for which partial results are expected by the end of this year, with final results expected in the second half of 2014. Future development plans include additional clinical studies in stem cell mobilization and chronic myeloid leukemia, which are expected to commence during the first half of 2014."

Professor Arnon Nagler, Director of Hematology and Bone Marrow Transplantation Division at Sheba Medical Center, Israel and the lead principal investigator of the study, commented, "The use of peripheral blood as a source of hematopoietic stem cells for transplantation in cancer patients after high-dose chemotherapy has largely replaced traditional bone marrow transplantation. In order for this treatment to succeed, a sufficient amount of stem cells needs to be mobilized from the bone marrow into the blood stream, preferably in the first mobilization attempt and ideally with a minimum of apheresis sessions. BL-8040 offers a real solution for this need, enabling robust and reproducible stem cell mobilization in multiple myeloma patients."

### **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 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 (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 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

### **About BioLineRx**

BioLineRx is a publicly-traded biopharmaceutical development company dedicated to building a portfolio of products for unmet medical needs, as well as those with advantages over currently available therapies. 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 is expected to commence a Phase 1/2 study in late 2013.

For more information on BioLineRx, please visit [www.biolinerx.com](http://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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