



## BioLineRx Receives Orphan Drug Designation for Novel Stem Cell Mobilization Treatment

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**- BL-8040 previously received Orphan Drug Designation for treatment of Acute Myeloid Leukemia -**

**- BL-8040 expected to commence Phase 1 trial in stem cell mobilization in Q2 2014; top-line results expected in H2 2014 -**

JERUSALEM, Jan. 23, 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 received notice from the U.S. Food & Drug Administration (FDA) confirming an Orphan Drug Designation of BL-8040 as a treatment for stem cell mobilization, in addition to the Orphan Drug Designation previously granted to BL-8040 as a treatment for Acute Myeloid Leukemia (AML).

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

Orphan Drug Designation is granted to therapeutics intended to treat rare diseases that affect not more than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to a seven-year marketing exclusivity period, clinical protocol assistance with the FDA, as well as federal grants and tax credits.

The Orphan Drug Designation was granted for use of BL-8040, in combination with granulocyte colony-stimulating factor (G-CSF), to mobilize human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation.

"We are very pleased to have our second Orphan Drug Designation for BL-8040, in this case for stem cell mobilization treatment, after already having received the designation last year for the treatment of acute myeloid leukemia," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "This is in line with our 2014 development plan for BL-8040, which includes clinical studies for both AML and stem cell mobilization. BL-8040 was already shown to be highly effective in mobilizing stem cells in combination with G-CSF in a Phase 1/2 study in multiple myeloma patients, and initial results of BL-8040's Phase 2 study for AML patients indicate that BL-8040 on a stand-alone basis triggers substantial mobilization of cancer cells from the bone marrow to the peripheral blood. We are eagerly looking forward to the results of the clinical trials in both indications expected in the second half of this year."

### 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. Stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), harvested from the peripheral blood by apheresis, and 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.

### 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 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](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.*

**Contact:**

[Tiberend Strategic Advisors, Inc.](#)

Joshua Drumm, Ph.D.

[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com)

(212) 375-2664

Andrew Mielach

[amielach@tiberend.com](mailto:amielach@tiberend.com)

(212) 375-2694

Or

Tsipi Haitovsky

Public Relations

+972-3-6240871

[tsipih@netvision.net.il](mailto:tsipih@netvision.net.il)

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