BioLineRx's BL-8040 Receives Orphan Drug Designation for Treatment of AML

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JERUSALEM, Sept. 9, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today that the U.S. Food & Drug Administration (FDA) has granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of acute myeloid leukemia (AML).

(Logo: http://photos.prnewswire.com/medias/switch.do?prefix=/appnb&page=/getStoryRemapDetails.do&prnid=20130730%252f630769&action=details)

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 market exclusivity period, clinical protocol assistance with the FDA, as well as federal grants and tax credits.

"We are very pleased to have received Orphan Drug Designation for BL-8040, which will facilitate the development process of one of our key clinical stage assets," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Currently, AML treatment options, especially in patients with a relapse of the disease, are extremely limited. BL-8040 has the potential to be a significant addition to the drug arsenal for this disease, especially when considering its promising pre-clinical results, unique biological mechanism and ability to synergize with other drugs already approved for this disease. Therefore, we are eagerly looking forward to the partial results of BL-8040's Phase 2 study expected towards the end of 2013," concluded Dr. Savitsky.

About BL-8040
BL-8040 is a clinical-stage drug candidate for the treatment of acute myeloid leukemia, as well as other types of hematological cancers. 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 late 2013; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers, 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 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:
KCSA Strategic Communications
Garth Russell / Todd Fromer
+1 212-896-1250 / +1 212-896-1215
grussell@kcsa.com / tfromer@kcsa.com

or

Tsipi Haitovsky
Public Relations
+972-3-6240871
tsipih@netvision.net.il

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