BioLineRx Presents Positive Preclinical Results of Acute Myeloid Leukemia Treatment at ASH Conference

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BL-8040 is currently in midst of Phase 2 study in AML patients, with partial results expected this month and final results expected in H2 2014 -

JERUSALEM, Dec. 10, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today that positive preclinical results of BL-8040 (formerly known as BKT-140), for the treatment of Acute Myeloid Leukemia (AML) and other hematological indications, have been presented as a poster at the 55th Annual Meeting of the American Society of Hematology (ASH). The data show that BL-8040 is efficient in inducing the death of AML cancer cells both *in vitro* and in a humanized mouse model.

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

BL-8040 is a novel, potent and selective inhibitor of the CXCR4 chemokine receptor, which is normally activated by the chemokine ligand CXCL12. Both CXCL12 and its receptor, CXCR4, are key players in enabling AML cancer cells to hide and thrive in the bone marrow, and CXCR4 expression in AML patients is associated with poor prognosis. FLT3 mutations are detected in approximately 30% of AML cases and are associated with poor prognosis and a high incidence of relapse in AML patients. In addition, expression of the CXCR4 receptor in FLT3 mutated AML is also correlated with poor outcomes. Accordingly, it is believed that inhibition of CXCR4 may sensitize AML cells toward chemotherapy and FLT-3 targeted therapies.

The data presented in the conference show that BL-8040 directly inhibits AML cell growth and induces cell death, both in cell cultures and in mice engrafted with human AML cells. In addition, the ability of BL-8040 to induce mobilization of AML cells from the bone marrow into the blood circulation enhanced the chemotherapeutic effect of ARA-C (one of the standard-of-care chemotherapies for AML). The effects were even more robust in cells harboring the FLT3 mutation and a synergistic effect was observed when BL-8040 was combined with the FLT3 inhibitor AC220 (Quizartinib).

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, "BL-8040, one of our key clinical-stage assets, is part of the personalized medicine revolution that aims to deliver precise, efficient therapy specifically tailored to each individual cancer patient. Indeed, the results presented in the ASH conference show that BL-8040 is highly effective in directly inducing AML cell death and in augmenting the effects of other drugs, resulting in an exceptionally high percentage of cell growth inhibition and death. These promising results further support the data we have accumulated to date, all indicating that BL-8040 has the potential to significantly improve personalized treatment for AML patients. We are looking forward to the partial results of the Phase 2 clinical trial in humans expected this month, with final results expected in the second half of 2014. Furthermore, based on the new pre-clinical data, we intend to perform a specific review of efficacy in the current Phase 2 study regarding those patients with the FLT3 mutation."

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 by the end of 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.

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