



BioLineRx Announces Positive Preclinical Results for Novel Treatment for Chronic Myeloid Leukemia

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- BL-8040 study published in Molecular Cancer Therapeutics -

- BL-8040 currently undergoing Phase 2 trial for acute myeloid leukemia (AML), and expected to commence Phase 1 trial in stem cell mobilization in Q2 2014; top-line results from both trials expected in Q4 2014 -

JERUSALEM, Feb. 12, 2014 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today positive pre-clinical results for BL-8040 in a third indication - as a treatment for chronic myeloid leukemia. Results of the study were recently published in [Molecular Cancer Therapeutics](#).

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

Chronic myeloid leukemia (CML) is a cancer of white blood cells that is driven by a constitutively active oncogenic tyrosine kinase. Tyrosine kinase inhibitors, such as imatinib mesylate (Gleevec), revolutionized the treatment of CML and remain a major therapeutic strategy for CML patients. However, dormant leukemic stem cells that are resistant to tyrosine kinase inhibitors and may be responsible for CML resistance and recurrence, are protected from therapy-induced cell death by the bone marrow microenvironment and in particular, by bone marrow stromal cells. Therefore, novel drugs are needed that can target leukemic stem cells in the bone marrow.

The study, led by Prof. Arnon Nagler, Director of the Hematology Division and Bone Marrow Transplantation Center at Sheba Medical Center, Israel, assessed the effect of BL-8040 alone, and in combination with imatinib, on the proliferation of human CML cells in culture and on human CML tumors that were engrafted in mice. Results of the study show that the BL-8040 treatment directly inhibited cancer cell growth and induced apoptotic cell death of CML cells in-vitro. Furthermore, BL-8040 had a synergistic effect with imatinib, enabling use of imatinib at low doses. In mice engrafted with CML tumors, the combination of BL-8040 with low-dose imatinib markedly inhibited tumor growth, achieving a 95% suppression. Most importantly, the novel drug reversed the protective effect of the bone marrow stroma on CML cells, effectively promoting their apoptosis.

"We are very pleased with the results of this study, which show that BL-8040 has the potential to be an important addition to the drug arsenal for CML," stated Prof. Nagler. "BL-8040 shows two intriguing properties. First, it can directly suppress CML cell proliferation, and second, it can sensitize CML cells that hide in the bone marrow to therapy-induced apoptosis. The second property mainly stems from the ability of this drug to flush out cancer cells from the bone marrow into the peripheral blood."

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, commented, "These encouraging results support the rationale for BL-8040 therapy, in combination with tyrosine kinase inhibitors, to override drug resistance and suppress residual disease. The study shows that BL-8040 has the potential to treat CML patients who have developed resistance to Gleevec. BL-8040 is currently undergoing a Phase 2 trial for AML and is expected to enter a Phase 1 trial for stem cell mobilization in the second quarter of this year, with top-line results for both of these studies expected in the fourth quarter of 2014. We have high hopes that this promising drug will realize its potential to help cancer patients, both as a stand-alone therapy and in combination with other therapies in the foreseeable future."

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-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; BL-7010 for celiac disease, which is in the midst of a Phase 1/2 study; and BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in the first half of 2014.

For more information on BioLineRx, please visit www.bioglinerx.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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