



BioLineRx Enrolls First Patient in Phase 2 Clinical Trial for BL-8040, for Treatment of Leukemia

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- Partial results expected in Q4 2013 -

JERUSALEM--(BUSINESS WIRE)--Jun. 6, 2013-- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today enrollment of the first patient in a Phase 2 trial for BL-8040, for the treatment of acute myeloid leukemia (AML). The patient was enrolled at the MD Anderson Cancer Center in Houston, Texas. The Company also announced that, in addition to receiving regulatory approval for commencing the trial in the U.S. this past April, it has also recently received regulatory approval from the Israeli Ministry of Health to conduct the trial in Israel. The activation of Israeli sites is anticipated during the next few weeks.

The study is a multicenter, open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in adult subjects with relapsed or refractory AML. The primary endpoints of the study are the safety and tolerability of BL-8040. Secondary endpoints include the pharmacokinetic profile of the drug and an efficacy evaluation, as assessed by various parameters, such as the response rate by bone marrow biopsy. The study is also designed in a way that will enable the investigators to evaluate the capabilities of BL-8040 in mobilizing cancer cells from the bone marrow to the peripheral blood, and in inducing their cell death. Up to 50 patients are expected to be enrolled in the study, which is expected to be conducted at 8 sites in the U.S. and Israel.

"We are very excited that BL-8040's Phase 2 trial has begun at a world-leading cancer research center such as MD Anderson," said Kinneret Savitsky, Ph.D., CEO of BioLineRx. "We anticipate that additional world-leading cancer research centers in the U.S. will join MD Anderson in this promising Phase 2 trial. In addition, the recently received regulatory approval from the Israeli Ministry of Health will also expedite recruitment of patients at several leading sites in Israel."

"The development of novel drugs for AML is critical, since treatment options for this common type of leukemia are still limited compared to other leukemia types. This is particularly apparent with respect to patients with relapsed or refractory diseases. Considering the compound's unique biological pathway and its promising pre-clinical results, BioLineRx and its clinical partners are enthusiastic about BL-8040. We have high hopes for BL-8040 and look forward to the partial results expected towards the end of this year," 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 other sites and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. It 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. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of seven clinical stage candidates: BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions has completed a Phase 1/2 study; BL-7040 for treating inflammatory bowel disease (IBD) has successfully completed a Phase 2a trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase 2 study; BL-1021 for neuropathic pain is in Phase 1 development; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; and BL-1020 for schizophrenia. In addition, BioLineRx has five products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development and commercialization. For more information on BioLineRx, please visit www.biolinerx.com, the content of which does not form a part of this press release.

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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