



BioLineRx Receives Regulatory Approval to Commence Phase II Clinical Trial for BL-8040, for Treatment of Leukemia

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Partial results expected in Q4 2013

Final results expected in H2 2014

JERUSALEM--(BUSINESS WIRE)--Apr. 10, 2013-- BioLineRx (NASDAQ:BLRX)(TASE:BLRX), a biopharmaceutical development company, announced today that it has received all necessary regulatory approvals in the US to commence a Phase IIa trial for BL-8040, for the treatment of Acute Myeloid Leukemia (AML).

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/refractory AML. The primary endpoints of the study are the safety and tolerability of the drug. Secondary endpoints will 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. The study is expected to be conducted in the U.S. and Israel, and will enroll up to 50 patients.

"This program is generating a lot of enthusiasm from our clinical research partners, and we are very pleased that several renowned and respected investigators will be leading our study in the U.S. and Israel," said Kinneret Savitsky, PhD, CEO of BioLineRx. "AML is one of the most common types of leukemia in adults, yet survival rates continue to be low relative to other leukemias. In particular, treatment options for patients with relapsed or refractory AML are extremely limited, and in many cases, only palliative care is offered. We look forward to the partial results expected towards the end of this year, and have sincere hopes that BL-8040 will be a significant and efficient addition in the battle with this devastating disease."

"We are honored to collaborate with BioLineRx on this exciting project," said Dr. Gautam Borthakur, the principal investigator of the trial at the MD Anderson Cancer Center in Houston, Texas. "BL-8040 has a unique mechanism of action and has shown very promising pre-clinical and clinical results. Specifically, in pre-clinical studies, BL-8040 showed a CXCR4-dependent, preferential anti-tumor effect against human-derived AML cells. Therefore, we are very pleased to be able to offer this novel therapeutic opportunity to our patients, particularly since AML is still such a big unmet medical need."

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 I/II, 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 six 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 I/II study; BL-7040 for treating inflammatory bowel disease (IBD) is currently undergoing a Phase II trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase II study; BL-1021 for neuropathic pain is in Phase I development; and BL-1020 for schizophrenia. In addition, BioLineRx has six 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 (Phase III) 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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