BioLineRx In-Licenses a Novel, Phase II Ready Drug for the Treatment of Leukemia and Other Hematological Cancers

- Phase II clinical trials are expected to commence in H1 2013 -

Jerusalem, Israel, September 4, 2012 --- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical drug development company, announced today that it has signed an exclusive, worldwide license agreement with Biokine Therapeutics Ltd., a Clal Biotechnology Industries (TASE: CBI) portfolio company, for the development and commercialization of BL-8040 (formerly BKT-140), a Phase II ready drug candidate for the treatment of acute myeloid leukemia (AML), as well as other types of hematological cancer.

BL-8040 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 16 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile and was well tolerated at all doses tested. On the basis of data obtained from this study, the FDA has approved an IND application.

BL-8040 has been shown to induce the mobilization of healthy hematopoietic stem cells from the bone marrow into the peripheral blood. BL-8040 also mobilizes cancer cells from the bone marrow and other sites and may therefore expose these cells to chemo- and bio-based anti-cancer therapy and induce 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.

Dr. Kinneret Savitsky, CEO of BioLineRx, commented, "BioLineRx has made a strategic decision to enter the field of oncology, where there is clearly an urgent need for next generation anti-cancer therapies utilizing novel biological pathways. We are therefore extremely pleased to in-license this promising Phase II ready drug, which we will initially develop for the treatment of acute myeloid leukemia, a true unmet medical need with very low survival rates. AML is a recognized orphan indication both in the U.S. and the EU; therefore, we plan to seek orphan designation status from the regulatory authorities in order to accelerate its development plan. In addition, based on BL-8040's promising pre-clinical data, as well its mechanism of action, we believe it can be utilized for several other related oncology indications and we intend to explore these possibilities as well. We look forward to the upcoming Phase II clinical study for evaluating BL-8040's efficacy on AML patients, which is expected to commence in the first half of 2013."

"We are very happy that BioLineRx will further develop this promising anti-cancer agent, and are confident that BioLineRx's experience and expertise will advance BL-8040 through the clinical development stages in the most efficient manner," said Professor Amnon Peled, from the Gene Therapy Institute, Hadassah Medical Center - Jerusalem, founder and CEO of Biokine Therapeutics.

"CXCR4 is one of the most important cancer targets discovered in recent years. It is essential for multiple aspects of cancer progression in over 70% of all cancers, including leukemia, breast, lung, colon, and prostate cancer. BL-8040, as a CXCR4 antagonist, therefore has the potential to target and kill various cancer cells, and studies in animal models of the disease have shown that this agent may stimulate hematological cancer cell death. In addition, for many blood cancers, the bone marrow provides protection for malignant cells from chemotherapeutic agents. Therefore, by inducing mobilization of these cells into the peripheral blood, CXCR4 antagonists literally 'flush out' the malignant cells from their hiding places.

"We have demonstrated in pre-clinical studies that BL-8040 is very effective in mobilizing cells out of the bone marrow, thus sensitizing chemo-resistant cells and improving treatment with other anti-cancer drugs," concluded Professor Peled.

Terms of the License Agreement

There are no upfront payments due pursuant to the agreement. BioLineRx is obligated to pay a monthly development fee ranging from $50K to $100K for certain development services that Biokine has committed to provide under the agreement. If the agreed-upon clinical development plan is completed within certain defined timelines, BioLineRx is obligated to pay Biokine a milestone payment of $250K. The agreement does not contain any other milestone payments. Upon any sub-licensing transaction to a third party, BioLineRx is required to pay Biokine a royalty payment on a sliding scale, beginning at 60% of the amounts received as consideration in connection with the sublicensing, and decreasing to 40% of such consideration, based on the aggregate amount of BioLineRx's investment in the project. Closing of the transaction is subject to formal approval of the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor.

About Acute Myeloid Leukemia (AML)

AML is a very aggressive form of leukemia, characterized by uncontrolled proliferation of immature white blood cells called myeloid cells in the bone marrow and peripheral circulation. AML is the most common form of adult acute leukemia, accounting for 80% of all diagnosed cases, with approximately 13,000 new cases diagnosed in the U.S., as well as 30,000 new cases diagnosed in the seven leading markets, in 2011. The incidence of AML is expected to further increase as the population of developed countries continues to age.

AML is currently treated with a combination of chemotherapeutic agents and stem cell transplantation. However, the past 20 years have seen little improvement in overall patient survival rates, which are less than 25% within five years from diagnosis. Accordingly, AML is considered a true unmet medical need and there is a significant urgency for developing more effective and tolerable treatments for AML patients, particularly those with relapsed or refractory disease. The AML therapeutics

market was estimated at $200 million in 2010, and it is projected to significantly grow with the development of new targeted therapies, reaching over $600 million by 2017. The total leukemia therapeutics market was valued at $6.3 billion in 2010, and is expected to reach $11.3 billion by 2020.

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

Various statements in this release concerning BioLineRx's future expectations, plans and prospects, 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 22, 2012. 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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