



## BioLineRx Announces Publication of Positive Pre-Clinical Results for BL-8040 in Treatment of Thrombocytopenia

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*- Results published in the [British Journal of Hematology](#) -*

*- BL-8040, currently in Phase 2 study for AML, continues to show promising results in other hematological indications -*

Jerusalem, August 5, 2013 - BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today that BL-8040 has been shown in pre-clinical trials to be effective for the treatment of thrombocytopenia, or reduced platelet production.

The findings were published in the [British Journal of Hematology](#), a leading journal in the field. The study, headed by Prof. Amnon Peled from the Goldyne Savad Institute of Gene Therapy - Hadassah University Hospital, assessed the effect of repeated doses of BL-8040 on healthy and chemotherapy-induced thrombocytopenic mice. The results show that repeated administration of BL-8040 significantly increased the number of megakaryocytes (cells that produce platelets) within the bone marrow; this was associated with increased production and increased levels of platelets in the blood circulation, in both the healthy and chemotherapy induced-thrombocytopenic mice. In addition, BL-8040 increased the number of hematopoietic progenitor cells within the bone marrow and in the blood. These cells are important for generating not only platelets but the whole gamut of red and white blood cells. In addition, BL-8040 significantly reduced the severity and duration of chemotherapy-induced thrombocytopenia and cytopenia.

"We are currently developing BL-8040 for acute myeloid leukemia (AML), and a Phase 2 clinical trial for this indication is underway at the MD Anderson Cancer Center in Houston and other leading centers in the U.S. and Israel," said Kinneret Savitsky, Ph.D., CEO of BioLineRx. "We have previously stated that we intend to pursue additional hematological indications for this promising asset. The results of this study, which provide evidence for the possible therapeutic use of BL-8040 for modulating platelet numbers in thrombocytopenic conditions, offer new possibilities which we may choose to explore further in pre-clinical and early-stage clinical trials. In addition, the ability of this novel drug to reduce thrombocytopenia, a frequent side effect of chemotherapy, makes BL-8040 even more appealing as a candidate for blood cancer treatment."

### **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 Thrombocytopenia**

Thrombocytopenia refers to reduced platelet production in the bone marrow and its accompanying peripheral blood. It is a challenging clinical scenario induced by a multitude of reasons, and commonly encountered among oncologic patients receiving high doses of chemotherapy. Thrombocytopenia increases risk of bleeding, and in severe cases is life threatening. In patients with a very low platelet count or in cases presenting with severe bleeding, the standard of care remains platelet transfusion, a costly procedure with associated risks due to immune reaction to the transfused cells and due to possible contaminating pathogens. It is therefore crucial to uncover novel therapeutic approaches that will reduce reliance on blood products.

One promising approach is to try and augment bone marrow platelet production and release prior to (or concomitant with) the administration of chemotherapeutic drugs. Previous research has suggested that stimulation of the TPO/thrombopoietin-receptor pathway, which is considered the master regulator of megakaryocyte production, may be an attractive strategy for increasing platelet count. However, the clinical effectiveness of TPO and TPO-related drugs in preventing bleeding and platelet transfusions, as well as their side effect profile, remain serious issues for concern. Thus, alternative pathways are continuously being explored.

### **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 completed a Phase 2a trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers has commenced a Phase 2 study; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; BL-1021 for neuropathic pain is in Phase 1 development; 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 (Phase 3) and commercialization. For more information on BioLineRx, please visit [www.biolinerx.com](http://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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