



## BioLineRx Announces Regulatory Submission for Phase 2b Trial for Novel AML Consolidation Treatment

March 2, 2015

**- BL-8040 Phase 2b study, as consolidation treatment for AML patients responding to standard induction treatment, is expected to commence shortly after receipt of regulatory approval, anticipated in next few months -**

JERUSALEM--(BUSINESS WIRE)--Mar. 2, 2015-- [BioLineRx Ltd.](#) (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the filing of regulatory submissions required to commence a Phase 2b trial for BL-8040 as a novel consolidation treatment for acute myeloid leukemia (AML). Due to BL-8040's unique properties, the Phase 2b study will examine its ability to improve outcomes for AML patients who have achieved remission after standard treatment by eliminating the minimal residual disease left in the bone marrow that can lead to relapse, known as consolidation therapy. The study is expected to commence shortly after the receipt of regulatory approval, which is anticipated in the next few months, and is the first of three additional planned clinical studies that significantly expand BioLineRx's unique BL-8040 platform for treating hematological cancers.

The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany. Regulatory submissions with BfArM, the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) and the relevant ethics committees have been made.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, "Without consolidation treatment aimed at destroying the remaining leukemic cells, AML is likely to return within several months of initial remission. The current principal options for AML consolidation therapy involve either several cycles of high-dose chemotherapy or stem cell transplantation. Based on positive results from our ongoing phase 2a clinical trial for BL-8040, which show substantial mobilization of AML cancer cells from the bone marrow to the peripheral blood, as well as induction of apoptosis of AML cells, we believe BL-8040 will be a promising addition to consolidation therapy for AML patients."

"Furthermore, BL-8040 has several unique mechanisms of action that enable it to positively affect various aspects of bone marrow function, both relating to healthy stem cells as well as to cancer cells. The breadth of BL-8040's potential is reflected in the comprehensive development plan we have established for this compound. We look forward to initiating this Phase 2b trial as well as our other planned studies for 2015, and to advancing this promising treatment platform for multiple hematological indications," 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 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. 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 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. Pre-clinical studies show that BL-8040 inhibits the growth of various tumor types, including multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small cell lung carcinoma, neuroblastoma and melanoma. In these studies, BL-8040 significantly and preferentially stimulated apoptotic cell death of malignant cells (multiple myeloma, non-Hodgkin's lymphoma and leukemia). Significant synergistic and/or additive tumor cell killing activity has also been observed in-vitro and in-vivo when tumor cells were treated with BL-8040 together with Rituximab, Bortezomib, Imatinib, Cytarabine and the FLT-3 inhibitor AC-220 (in NHL, MM, CML, AML, and AML-FLT3-ITD models, respectively). In addition, the current Phase 2a clinical trial in AML patients has demonstrated robust mobilization and apoptosis of cancer cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

### **About Acute Myeloid Leukemia (AML)**

Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. According to the American Cancer Society, approximately 14,500 new cases of AML were diagnosed in the United States in 2013, and the median age of AML patients was 66 years old. AML is usually treated in two phases - the induction and consolidation phases. Induction treatment is aimed at eradicating all visible leukemic cells, resulting in initial remission, while consolidation treatment is aimed at destroying any remaining leukemic cells. The median survival for patients receiving induction chemotherapy, which is associated with high mortality, is 6-12 months, with shorter survival for patients over the age of 60 or for those with certain gene or chromosome aberrations. The five-year survival rate for AML is 10-30 percent, due to relapsed or refractory disease associated with standard treatments.

### **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 Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2

study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

For more information on BioLineRx, please visit [www.biolinrx.com](http://www.biolinrx.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 17, 2014. 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.*

Source: BioLineRx Ltd.

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