



## BioLineRx Presents Positive Preclinical Results in Treatment for AML Patients with FLT3 Mutations

September 17, 2014

- Results in this additional indication for BL-8040 presented at Society of Hematologic Oncology (SOHO) Annual Meeting -

- BL-8040 also undergoing Phase 2 study in AML, with final results expected in early 2015; and Phase 1 study in stem cell mobilization, with results expected by year-end 2014 or early 2015 -

JERUSALEM--(BUSINESS WIRE)--Sep. 17, 2014-- [BioLineRx Ltd.](#) (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the presentation of positive preclinical results of its BL-8040 cancer therapy platform, as a novel treatment for a sub-population of acute myeloid leukemia (AML patients with FLT3 mutations), at [the Society of Hematologic Oncology \(SOHO\) 2014 Annual Meeting in Houston, Texas](#). The data show that BL-8040 synergizes with another AML drug in development, the FLT3 inhibitor AC220, to reduce minimal levels of residual disease in the bone marrow of an AML mice model with the FLT3-ITD-mutation.

BL-8040 is a novel, potent and selective inhibitor of the CXCR4 chemokine receptor, which is normally activated by the chemokine ligand CXCL12. Both CXCL12 and its receptor, CXCR4, are key players in enabling AML cancer cells to hide and thrive in the bone marrow, with CXCR4 expression in AML patients being associated with a poor prognosis. FLT3 mutations are detected in approximately 30% of AML cases and are associated with a poor prognosis and high incidence of relapse in AML patients. FLT3 mutations have also been shown to activate CXCR4 signaling and are associated with increased CXCR4 expression. Accordingly, it is believed that inhibition of CXCR4 may sensitize AML cells to chemotherapy and FLT-3 targeted therapies.

The data presented during the conference show that BL-8040 rapidly and efficiently induces cell death of AML cells both *in-vitro* and *in-vivo*. Additionally, the combination of BL-8040 with the FLT3 inhibitor AC220 (Quizartinib) *in-vitro* increased the apoptotic effect of AC220, from a 60% reduction to a 97% reduction in AML cell viability. *In-vivo*, BL-8040 also augmented the effect of AC220, reducing the level of residual AML cancer cells in the bone marrow from 0.05% to as low as 0.006%, eliminating the disease altogether in some mice from this treatment group. Importantly, reduction of the disease burden in the BL-8040 and AC220 combination therapy group resulted in prolonged survival. Furthermore, the addition of BL-8040 in the combination therapy group also mitigated the reduction in normal white blood cells observed when administering the AC220 treatment on a stand-alone basis.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, "BL-8040, our clinical-stage cancer therapy platform, supports the personalized medicine revolution that aims to deliver precise, efficient therapy specifically tailored to individual cancer patients. The results reported today show that the combination of BL-8040 and AC220 reduces the minimal residual disease of AML cells in treated mice and also increases their survival. These results support potential therapeutic advantages of BL-8040 in AML patients with the FLT3-ITD-mutation, and provide a rational basis for administering BL-8040 therapy in combination with FLT3 inhibitors in this patient population. These promising results further support the data we have accumulated to date - all indicating that BL-8040 has the potential to significantly improve treatment for AML patients."

BL-8040 is currently undergoing a Phase 2 clinical trial in adult AML patients with relapsed or refractory AML, the results of which are expected in early 2015. Concurrently, a Phase 1 stem cell mobilization study for BL-8040 is ongoing, with results expected by the end of 2014 or the beginning of 2015; and an investigator-led Phase 1/2 study for BL-8040 in Chronic Myeloid Leukemia (CML) is expected to commence in 2014.

### 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 (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. In addition, the current Phase 2 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 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 is in the final stages of a Phase 1/2 study.

For more information on BioLineRx, please visit [www.biolinerx.com](http://www.biolinerx.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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