



BioLineRx Files Protocol Amendment to Phase 2 Study for AML Treatment based on Encouraging Efficacy and Strong Safety Profile

November 3, 2014

- Amendment will include testing of higher doses, resulting in increase of total study population to up to 70 patients -

- Changes unanimously recommended by Clinical Advisory Board -

JERUSALEM--(BUSINESS WIRE)--Nov. 3, 2014-- [BioLineRx Ltd.](#) (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that in light of encouraging pharmacodynamic and excellent safety data from the ongoing Phase 2 clinical trial of BL-8040 for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML), the Company has filed with the U.S. Food and Drug Administration (FDA) an amendment to the study protocol to test additional cohorts at higher doses in the current dose-escalation stage of the trial. The amendment will also include an increase in the total expected study enrollment, from up to 50 under the original protocol, to up to 70 patients.

BL-8040 was found to be safe at all doses tested to date, with no serious adverse events related to BL-8040. Results from the trial to date continue to show substantial mobilization of leukemic cells from the bone marrow and robust induction of cancer cell apoptosis. The decision to add higher dosing cohorts, in order to determine the optimal dose to use in the upcoming expansion stage of the trial, was based on a unanimous recommendation from BL-8040's Clinical Advisory Board (CAB).

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, "BL-8040, one of our lead clinical programs, is a promising cancer therapy platform for the treatment of a variety of hematological indications. We are already very pleased with the encouraging pharmacodynamic data demonstrated in our ongoing Phase 2 AML study, which suggest a significant therapeutic window. In light of the excellent safety data to date and the recommendation of our advisors, the current amendment will enable us to further increase BL-8040's dosing, thereby continuing to enhance its potential efficacy."

"Since we plan to increase the number of patients in the dose escalation stage, in order to maintain the adequate number of patients originally planned in the dose expansion stage, we have decided to increase the overall sample size of the study to 70 patients. This will enable treatment of at least 40 patients at the optimal dose. We now expect to complete the dose escalation stage of the study by early next year, and the full study, following the expansion stage, in the second half of 2015. BL-8040 is also in the midst of a Phase 1 stem cell mobilization study, with results expected by early 2015," concluded Dr. Savitsky.

About BL-8040's Phase 2 Trial

The Phase 2 trial is a multicenter, open-label study under an IND, conducted at eight clinical sites in the U.S. and Israel, and is designed to evaluate the safety and efficacy of repeated doses of BL-8040 in adult patients with relapsed or refractory AML. The primary endpoints of the study are the safety and tolerability of BL-8040. Secondary endpoints include the pharmacokinetic profile of the drug and an efficacy evaluation, indicated by the extent of mobilization of cancer cells from the bone marrow to the peripheral blood, the level of cancer cell death (apoptosis) and clinical responses.

The study is comprised of two parts – the current dose escalation stage and a subsequent expansion stage at the optimal dose determined during the escalation stage. During the dose escalation stage, trial participants are generally recruited in cohorts of three patients at a time, and the dose is increased for each subsequent cohort depending on the safety and tolerability results of the previous cohort, as confirmed by an independent Data Safety Monitoring Board. To date, there have been no serious adverse events related to BL-8040 up to and including the fourth dosing level in the study of 1.25 mg/kg, with the primary adverse event being a transient reaction at the injection site. The study is currently in the fifth and final dosing level originally planned in the study of 1.5 mg/kg. Due to the fact that BL-8040 was found safe at all doses tested to date, and based on the recommendation of the CAB, the Company intends to add additional cohorts to the current dose escalation stage of the study, in order to determine the optimal dose for the remainder of the study.

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 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 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. The frontline treatment for patients with AML includes systemic combination induction chemotherapy. 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 is in the final stages of a Phase 1/2 study.

For more information on BioLineRx, please visit www.bioplinerx.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.

[Tiberend Strategic Advisors, Inc.](http://TiberendStrategicAdvisors.Inc)

Joshua Drumm, Ph.D., +1-212-375-2664

jdrumm@tiberend.com

or

Andrew Mielach, +1-212-375-2694

amielach@tiberend.com

or

Tsipi Haitovsky, +972-3-6240871

Public Relations

tsipihai5@gmail.com