BioLineRx Announces Initiation of Phase 2b Trial for Novel AML Consolidation Treatment

August 17, 2015

- Phase 2b study, as consolidation treatment for AML patients responding to standard induction treatment, will enroll up to 194 patients, randomized in 1:1 ratio, at up to 25 sites in Germany -

- Study is first of three additional clinical studies for BL-8040 platform expected to commence during 2015 -

TEL AVIV, Israel--(BUSINESS WIRE)--Aug. 17, 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 initiation of a Phase 2b trial for BL-8040 as a novel consolidation treatment for acute myeloid leukemia (AML). The Phase 2b study will examine BL-8040 as part of a second stage treatment, termed consolidation therapy, to improve outcomes for AML patients who have achieved remission after the standard initial treatment regimen, known as induction therapy. The consolidation therapy is aimed at eliminating the minimal residual disease left in the bone marrow after induction therapy that can lead to relapse. This study is the first of three clinical studies in additional indications for BL-8040 which BioLineRx plans to commence during 2015, thus significantly expanding its unique BL-8040 oncology platform.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, “The majority of high-risk AML patients achieving first complete remission relapse within one year, despite the current standard consolidation therapy. Patients with AML relapse have a poor prognosis despite further therapy, and less than 10% of these patients are cured by conventional therapy. Leukemic stem cells that are dormant in the bone marrow are presumed to be a major reason for AML relapse. Based on the pre-clinical and clinical data accumulated to date, BL-8040 is anticipated to boost the efficacy of consolidation therapy due to its dual mechanism of action. Firstly, BL-8040 induces mobilization of leukemic cells from the bone marrow, which enhances the cytotoxic effects of chemotherapy, and secondly, it possesses anti-leukemic pro-apoptotic properties that help eliminate AML cells directly. Based on positive results from our ongoing phase 2 clinical trial for BL-8040, which show substantial mobilization of AML cells from the bone marrow to the peripheral blood, as well as robust induction of AML cell apoptosis, we believe BL-8040 will be a promising addition to consolidation therapy for AML patients.”

Dr. Savitsky added, “In addition to initiation of the Phase 2b AML consolidation study, we are eagerly looking forward to the top-line results from our ongoing Phase 2 study of BL-8040 for treating relapsed and refractory AML patients, which we expect in the fourth quarter of 2015. We also look forward to the next stages of development for BL-8040 as a novel stem cell mobilization treatment, after its recent successful completion of a Phase 1 trial. Finally, we are also excited about the anticipated initiation of clinical studies for BL-8040 in two additional indications over the next few months, thus further expanding and enhancing the potential of our oncology platform.”

The Phase 2b trial, which is conducted in collaboration with the University of Halle as sponsor and with the participation of two large leukemia study groups in Germany, is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. The primary endpoint of the study is to compare the relapse free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements will be conducted in order to assess the minimal residual disease, and biomarker analyses will be performed to identify predictors of BL-8040 response. The study will enroll up to 194 patients at up to 25 sites in Germany. AML patients between 18 and 75 years of age with documented first remission will be randomized in a 1:1 ratio to receive high dose Cytarabine, either with BL-8040 or with a matching placebo, as consolidation therapy.

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, when combined with G-CSF, 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. Additionally, in a Phase 1 stem-cell mobilization study in healthy volunteers, BL-8040 as a single agent was safe and well tolerated at all doses tested and resulted in efficient stem-cell mobilization and collection in all study participants. Importantly, the results of this study support the use of BL-8040 as one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care.

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. 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 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 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 19,000 new cases of AML were diagnosed in the United States in 2014, and the median age of AML patients was 67 years old. The first treatment line for patients with AML includes a combination of chemotherapy drugs and is called induction treatment. The median survival for AML patients receiving induction chemotherapy is less than two years, with shorter survival for patients over the age of 60 or for those with certain gene or chromosome aberrations. Due to relapsed or refractory disease (where the disease is not responsive to

standard treatments), the overall five-year survival rate for AML is between 10 and 40 percent.

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-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML), and has successfully completed a Phase 1 study in stem cell mobilization; BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study; and BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria).

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.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 23, 2015. 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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Source: BioLineRx Ltd.

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