



BioLineRx Initiates Expansion Stage of Phase 2 Clinical Trial for Novel Treatment for Acute Myeloid Leukemia

May 4, 2015 11:01 AM IDT

BL-8040 remains safe and well tolerated at highest dose; continues to induce robust mobilization and leukemia cell death

Top-line results expected Q4 2015

JERUSALEM--(BUSINESS WIRE)--May 4, 2015-- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today successful completion of the dose escalation stage of its ongoing Phase 2 study of BL-8040, and commencement of the expansion stage at the optimal dose of this novel treatment for acute myeloid leukemia (AML). Top-line results from the study are anticipated in the fourth quarter of 2015.

Results of the completed dose escalation stage, in which 22 patients participated, showed that all BL-8040 tested doses, up to 1.5 mg/kg, were found to be safe and well tolerated when administered in combination with Ara-C (Cytarabine). Building upon prior interim results, which included doses up to 1.25 mg/kg and were presented at the 2014 American Society for Hematology conference, the data indicate that BL-8040 exhibits robust single-agent activity, with a dramatic decrease in the amount of AML cells in the bone marrow and significant mobilization of these cells into the peripheral blood following two days of BL-8040 monotherapy, as well as direct induction of leukemia cell death. Based on the study's pharmacodynamic data, 1.5 mg/kg was chosen as the dose for use in the expansion stage of the study. In parallel to initiation of the expansion stage, additional patients will be recruited to assess one higher dose level of BL-8040, in order to further expand the therapeutic window of the drug.

"We are greatly encouraged by these interim results and are excited to commence the final stage of this important trial," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "We expect this stage to progress much more quickly than the dose-escalation stage of the trial, which required approval from the data safety monitoring committee before moving to the next dose level. We also expect to open additional sites for this stage of the trial. We look forward with much anticipation to announcing top-line results of the trial, which we expect in the fourth quarter of this year."

Dr. Savitsky continued, "Our expanding BL-8040 platform continues its track record of impressive achievements, including the recently reported successful top-line results from our Phase 1 safety and efficacy study for stem cell mobilization. We expect to provide the full set of results from this study at the European Hematology Association (EHA) Congress being held next month in Vienna, Austria. In addition, as previously reported, we expect to commence clinical trials for three additional indications for BL-8040 in the next few months."

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 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) and has just completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a

Phase 1/2 study.

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.



Source: BioLineRx Ltd.

Tiberend Strategic Advisors, Inc.
Joshua Drumm, Ph.D., 212-375-2664
jdrumm@tiberend.com

or

Andrew Mielach, 212-375-2694
amielach@tiberend.com

or

Tsipi Haitovsky
Public Relations
+972-3-6240871
tsipihai5@gmail.com