BioLineRx Announces Promising Initial Phase 2 Results of Acute Myeloid Leukemia Treatment

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- Initial results for BL-8040 show substantial mobilization of cancer cells and signs of robust cancer cell death (apoptosis) -

JERUSALEM, Dec. 16, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today promising initial results for its BL-8040 drug candidate in a Phase 2 clinical trial for patients with relapsed or refractory acute myeloid leukemia (AML). The early results show that BL-8040, as a stand-alone therapy and in combination with high-dose Cytarabine (Ara-C), is safe at all doses tested to date, and triggers substantial mobilization of cancer cells from the bone marrow to the peripheral blood, thereby increasing the vulnerability of the cells to chemotherapy treatment. In addition, signs of robust apoptosis (cell death) of cancer cells were observed following administration of the higher doses tested to date. The study has not yet reached the highest planned doses, suggesting that a strengthening of BL-8040's effects may be observed in future dosing cohorts.

(Logo: http://photos.prnewswire.com/prnh/20130730/630769)

The Phase 2 trial is a multicenter, open-label study under an IND, and is designed to evaluate the safety and efficacy of repeated escalating doses of BL-8040 in adult patients with relapsed or refractory AML. The primary endpoints of the study are to assess 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.

Eight patients have already been enrolled in the study, out of a total expected enrollment of up to 50 patients at eight clinical sites in the U.S. and Israel. The study is comprised of two parts – the current dose escalation phase and a subsequent expansion phase at the highest tolerated dose found during the escalation phase. During the dose escalation phase, trial participants are 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. To date, there have been no serious adverse events related to BL-8040, while the primary adverse event has been a minor and transient reaction at the injection site. The BL-8040 dosing level of the current study cohort is 1 mg/kg, with the highest planned study dose being 1.5 mg/kg.

"We are very excited about the initial results from the Phase 2 trial of BL-8040 in relapsed and refractory AML patients. This is one of our most promising clinical-stage assets, and these results provide further support for the potential of this unique drug," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Although the trial is at an early stage and we have not yet completed the dose-escalation assessment, we already see impressive mobilization of cancer cells from the bone marrow into the blood stream at a rate that is markedly higher than that seen with other drugs tested for this indication. In addition, there are initial signs of robust apoptosis of cancer cells, similarly to what we have seen in pre-clinical studies.

"The dose escalation phase of the study requires a safety and tolerability assessment by an outside Data and Safety Monitoring Board prior to advancing to the next dose level, while the expansion phase will proceed at the optimal dose without the need for such assessment. Therefore, we expect the expansion phase of the study to proceed at a significantly faster pace than the dose escalation phase. We are looking forward to reporting further interim results at the end of the dose escalation phase, expected during the second quarter of 2014, with final study results expected in the second half of 2014. Future development plans for BL-8040 include entering into additional hematological indications, including the commencement of clinical studies in stem cell mobilization and chronic myeloid leukemia during the first half of 2014."

Dr. Gautam Borthakur, the principal investigator from the world-renowned MD Anderson Cancer Center in Houston, stated, "AML is a disease with a clear need for new and more effective treatments. Current options are rather limited, and the five-year survival rate is low compared to many other blood cancers. This is particularly true with respect to patients with relapsed or refractory diseases. The initial results of the BL-8040 Phase 2 trial show a remarkable apoptotic effect of the drug on AML cancer cells, and the drug is exceptional in its ability to induce both mobilization of cancer cells from the bone marrow, as well as a concomitant cell death effect. I therefore have high hopes that this drug will become an important addition to the limited drug arsenal for AML treatment."

About BL-8040
BL-8040 is a clinical-stage drug candidate for the treatment of acute myeloid leukemia and 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 retention of cancer cells in the bone marrow, 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 therapy as well as 'targeted' 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. 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 will be diagnosed in the United States in 2013, with 66 being the median age of AML patients. 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 Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in early 2014; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which is expected to commence a Phase 1/2 study by the end of 2013.

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 12, 2013. 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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