



BioLineRx Presents Multi-Year Clinical Development Plan for its BL-8040 Hematological Cancer Therapeutic Platform

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- Clinical trials in three additional indications for BL-8040 to be initiated in 2015 -

- Development strategy presented today at BioLineRx investor meeting in New York -

NEW YORK--(BUSINESS WIRE)--Dec. 12, 2014-- During an investor and analyst meeting hosted today in New York, [BioLineRx Ltd.](#) (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, will disclose its multi-year development plan for BL-8040, a unique platform for the treatment of hematological cancers.

The main development program for BL-8040 relates to acute myeloid leukemia (AML). BL-8040 is currently undergoing a Phase 2a clinical trial for the treatment of relapsed or refractory AML. Positive data from the dose-escalation stage of the study, which was recently presented at the 2014 ASH (American Society of Hematology) Conference, has shown substantial mobilization of AML cancer cells from the bone marrow to the peripheral blood and robust apoptosis of these cells, as well as an excellent safety and tolerability profile. The dose-escalation stage of the study is expected to be completed in early 2015, while the full study results from both the dose-escalation and dose-expansion stages of the study are expected in the second half of 2015.

Targeting a second AML treatment line, BL-8040 is scheduled to commence a Phase 2b trial, as a consolidation treatment for AML patients who have responded to standard induction treatment, in the first quarter of 2015. The trial will be conducted in collaboration with the German Study Alliance Leukemia Group. The trial aims to improve the response of AML patients to the second stage of AML treatment, termed consolidation therapy, by eliminating the minimal residual disease left in the bone marrow after the first stage of the standard treatment regimen, called induction therapy.

BL-8040 will also target a third population of AML patients, and is scheduled to commence a Phase 1/2 trial, for the treatment of AML patients with the FLT3-ITD mutation, in the first quarter of 2015. AML patients with the FLT3-ITD mutation exhibit poor response and high relapse rates to chemotherapy, and only transient response rates to FLT3 inhibitors. Preclinical data (presented at the European Hematology Association Conference in June 2014) show that by inhibiting the CXCR4 receptor, BL-8040 enhances the effect of FLT3 inhibition in killing FLT3-mutated leukemic cells. The Phase 1/2 trial, which will be conducted in collaboration with the MD Anderson Cancer Center, is aimed at improving the response of FLT3-ITD mutated AML patients to treatment with sorafenib (a FLT3 inhibitor). Patients testing positive for the FLT3-ITD mutation will receive several treatment cycles of BL-8040 and sorafenib in combination. The safety of the combination treatment, as well as the response rate to the treatment and the duration of the response will be evaluated.

A second clinical development program planned for BL-8040 designates the drug for the treatment of hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (AA). hMDS is a subtype of myelodysplastic syndrome, a collection of myeloid malignancies characterized by one or more peripheral blood cytopenias (deficiency in the number of blood cells). AA is a disease in which the bone marrow and the blood stem cells that reside in the marrow are depleted, resulting in a deficiency of all three blood cell types: red blood cells, white blood cells, and platelets. Treatment for these bone-marrow failure conditions consists of immunosuppressive therapy with hATG and cyclosporine; however, a sizable fraction of patients do not respond to this therapy. Preclinical data suggest that BL-8040 promotes stem cell proliferation and differentiation thereby allowing recovery of hematopoiesis (formation and development of blood cells). The data show that treatment of mice with BL-8040 contributes to bone marrow regeneration, and increases the number of progenitor cells and the mature components of the blood and immune systems. BioLineRx is planning to commence a Phase 1/2 trial, to assess the addition of BL-8040 to the standard immunosuppressive therapy in patients with hMDS or AA, in the second quarter of 2015. This trial will be conducted in collaboration with the MD Anderson Cancer Center.

A third clinical development program for the BL-8040 treatment platform involves assessing the drug as a novel monotherapy treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation, where they can be harvested for transplant supporting the treatment of hematological indications. Stem cell mobilization is increasingly used as a method of collecting hematopoietic stem cells for transplantation, as part of the treatment of certain types of hematological cancers, and for the treatment of severe anemia or immune deficiency disorders. A two-part Phase 1 study is currently ongoing, to explore the safety, tolerability, pharmacodynamic and pharmacokinetic effects of ascending doses of BL-8040 in healthy subjects. The results of this study are expected in the first quarter of 2015.

"We are proud to present our multi-year vision for BL-8040, our unique platform for the treatment of hematological malignancies and other hematological indications," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "BL-8040 has unique mechanisms of action that enable it to positively affect various aspects of bone marrow function, both relating to healthy stem cells as well as to cancer cells. The breadth of its effects requires a comprehensive development plan, and this is reflected in a number of important strategic collaborations that we have entered into with leading institutions in the US and in Europe. We look forward to reporting the results of our currently ongoing clinical trials, and to initiating several new clinical trials for this promising therapeutic platform, during 2015."

BioLineRx will host an event for investors and analysts this morning from 8:00-10:00 a.m. EST in New York to present more details regarding its multi-year clinical development strategy for BL-8040. The event will also include a keynote presentation by Dr. Jorge Cortes, Distinguished Professor of Leukemia Research at the MD Anderson Cancer Center in Houston, Texas, titled "Current Developments in the AML Treatment Space." An audio of the presentations delivered will be available via a live webcast posted on the "[Upcoming Events](#)" page of BioLineRx's website, and the presentation materials will also be posted on the same page of the [website](#).

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 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 has successfully completed a Phase 1/2 study.

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

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