BioLineRx Announces Issuance of United States Patent Covering Use of BL-8040 in Immunotherapy

March 14, 2014

- BL-8040 currently undergoing Phase 2 trial for acute myeloid leukemia (AML), and expected to commence Phase 1 trial in stem cell mobilization in Q2 2014 -

- Top-line results from both trials expected in next 9-12 months -

JERUSALEM--(BUSINESS WIRE)--Mar. 14, 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 an Issue of Notification has been received from the United States Patent and Trademark Office (USPTO) for U.S. Patent No. 8,663,651, which includes claims to protect the use of BL-8040's composition for enhancing immune responses to an antigen, such as a tumor-associated antigen. The issued patent has a term extending to October 2029. This patent is part of BL-8040's expanding patent portfolio, which includes 13 issued patents and 25 patent applications pending worldwide, providing a strong intellectual property estate around BL-8040.

"We are very pleased with this newly issued patent for BL-8040, which further strengthens the patent position we have for our leading oncology program. We view BL-8040 as a platform for multiple oncological and hematological indications, and robust patent protection provides us with the foundation to pursue these multiple indications for the BL-8040 platform," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "BL-8040 is currently undergoing a Phase 2 trial for the treatment of acute myeloid leukemia and is expected to enter a Phase 1 trial for stem cell mobilization in the 2nd quarter of 2014. We expect top-line results for both of these clinical studies towards the end of the year or early next year," concluded Dr. Savitsky.

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. BL-8040 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 (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 also mobilizes stem cells from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. 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 combination with G-CSF in the mobilization of hematopoietic stem cells and white blood cells from the bone marrow to the peripheral blood. 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; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; BL-7010 for celiac disease, which is in the midst of a Phase 1/2 study; and BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in the first half of 2014.

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.

Source: BioLineRx Ltd.

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