BioLineRx Announces Presentation of Detailed Mechanism of Action Data for Lead Oncology Platform at AACR 2016

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- Results identify specific targets in the apoptotic pathway -

TEL AVIV, Israel, April 19, 2016 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX) announced today that detailed results from a study on the underlying mechanism of action of BL-8040, its lead platform for the treatment of multiple cancer and hematological indications, were presented by Prof. Amnon Peled at the American Association of Cancer Research (AACR) 2016 meeting in New Orleans.

The work presented, entitled "*CXCR4 Controls BCL-2 Expression and Function by Regulating miR-15a/16-1 Expression in Tumor Cells,*" illustrates the mechanism by which the CXCR4 pathway controls malignant cell survival and death in preclinical studies. Specifically, the studies point out how BL-8040 increases the expression and activity of a special class of microRNA precursors termed miR-15a/16-1. These microRNA molecules have been previously linked to cancer, and shown to suppress the activity of several tumor-related pro-survival proteins, specifically BCL2, MCL1 and cyclin D1. The studies presented showed that BL-8040 increases the suppression of these three target proteins through miR-15a/16-1, thereby increasing tumor cell death.

The BL-8040 oncology platform is a short cyclic peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is overexpressed in the majority of cancer cells, and its degree of expression often correlates with disease severity.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, "We recently announced the successful top-line results for BL-8040, in combination with Cytarabine, one of the standard-of-care chemotherapies, in a Phase 2 study in relapsed or refractory AML. In that study, BL-8040 showed a triple effect on the leukemic cells. First, BL-8040 monotherapy triggered robust mobilization of AML cells from the bone marrow to the peripheral blood, thereby sensitizing these cells to the chemotherapy and improving its efficacy. Second, BL-8040 monotherapy showed a 3-4 fold increase in the direct apoptotic effect on the leukemia cells in the bone marrow. Last, BL-8040 monotherapy induced leukemia progenitor cells towards differentiation. As a result of these factors, we reported a 38% complete remission rate in the study, compared to historical remission rates in similar patient populations with similar treatment regimens of approximately 20% for Cytarabine on a stand-alone basis. We look forward to providing the full results of this study at an upcoming scientific conference."

"In this regard, we are pleased to announce the current study results presented at the AACR meeting, which provide significant clarity regarding BL-8040's mechanism of action relating to apoptosis. The data suggest that BL-8040 is able to indirectly suppress the activity of several tumor-promoting genes, by increasing the activity of the microRNA molecule miR-15a/16-1. Of note, one of these pro-survival proteins, BCL-2, is a validated anti-cancer target that is recently attracting a lot of interest in the drug development space."

"In order to further expand and enhance the potential of our unique oncology platform, BL-8040 is undergoing multiple clinical studies, including our recently announced immuno-oncology collaboration with Merck on a Phase 2 study to investigate BL-8040 in combination with KEYTRUDA® for the treatment of pancreatic cancer," concluded Dr. Savitsky.

Link to AACR On-Line Abstract

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 cyclic 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 also 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 recently completed Phase 2 clinical trial in AML patients has demonstrated robust mobilization and apoptosis of cancer cells, along with a clinically meaningful response rate. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About BioLineRx
BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2 study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease and gluten sensitivity, which has successfully

completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2 study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

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 10, 2016. 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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