



## BioLineRx Announces Partial Monotherapy Results from Phase 2a COMBAT Study in Pancreatic Cancer

January 17, 2018

**- BL-8040 monotherapy resulted in increased infiltration of T cells into tumor -**

**- Data to be presented at the upcoming ASCO-GI conference; topline clinical results expected by H2 2018 as planned -**

TEL AVIV, Israel, Jan. 17, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today partial results from the monotherapy portion of BL-8040's Phase 2a COMBAT study showing that BL-8040 increases infiltration of T cells into the tumor in patients with metastatic pancreatic cancer. The data will be presented as a poster titled "[Evaluation of Pharmacodynamic Biomarkers in Patients with Metastatic Pancreatic Cancer Treated with BL-8040, a Novel CXCR4 Antagonist \(Abstract 276\)](#)" at the ASCO 2018 Gastrointestinal Cancers Symposium, on January 19, 2018 in San Francisco, CA.

The partial results from the BL-8040 monotherapy portion of the COMBAT trial show that BL-8040 was safe and well-tolerated. BL-8040 also induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood regulatory T cells (Tregs), known to impede the anti-tumor immune response, was decreased. In addition, analysis of available biopsies (N = 7) showed infiltration of various types of effector T cells, known to attack cancer cells, into the tumor periphery and tumor micro-environment (TME). In this regard, the results show up to a 15-fold increase in CD3+ T cells, and up to a 2-fold increase in CD8+ T cells, in the TME of 43% (3/7) of the patients, after five days of BL-8040 monotherapy.

Dr. Manuel Hidalgo, Chief of Hematology Oncology and Co-Director of the Pancreatic Cancer Research Program at Beth Israel Deaconess Medical Center in Boston, commented, "This is the first time we see results of BL-8040 in pancreatic cancer patients. The results of the monotherapy part of the COMBAT trial are extremely encouraging as they confirm the mechanism of action of BL-8040 in this difficult-to-treat patient population, resulting in T-cell infiltration into the tumor after only 5 days of monotherapy with BL-8040. These results support the rationale for combining BL-8040 with checkpoint inhibitors, and I am looking forward to the topline results of the COMBAT study expected later this year."

"The results show that BL-8040 induces robust infiltration of anti-tumor T cells into liver metastases in almost half of the pancreatic cancer patients who underwent a biopsy, effectively transforming these tumors from immunologically 'cold' to 'hot', which is seen as key in the objective of improving the responsiveness of patients with pancreatic cancer to front-line immunotherapy" stated Philip Serlin, Chief Executive Officer of BioLineRx. "These results support the mechanism of action proposed by pre-clinical studies, namely that BL-8040 mobilizes immune cells into the peripheral blood and promotes T cell infiltration into tumors. As previously reported, enrollment of the study has been completed and we expect to meet our timelines for conclusion of the study and topline results by the second half of 2018."

The Phase 2a study, named the COMBAT study, is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of the combination of BL-8040 and KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in over 30 subjects with metastatic pancreatic adenocarcinoma. The study is primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies. In addition, the study evaluates multiple pharmacodynamic parameters, including the ability to increase infiltration of T cells into the tumor, for both BL-8040 as a monotherapy, as well as for the combination of BL-8040 and KEYTRUDA. The study is being conducted in the US, Israel and additional territories.

The COMBAT study is being conducted by BioLineRx under a collaboration agreement signed in 2016 between BioLineRx and MSD, through a subsidiary, to support a Phase 2a study investigating BioLineRx's BL-8040 in combination with KEYTRUDA in patients with metastatic pancreatic cancer.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells to peripheral blood and to be effective at inducing direct tumor cell death. Additional findings have suggested that CXCR4 antagonists may be effective at increasing the infiltration of anti-tumor T cells into tumors that were previously immunologically "cold" and devoid of immune cell infiltrate. Checkpoint inhibitors (such as KEYTRUDA) produce anti-cancer effects by increasing the activity of T cells through blockade of the interaction between the immunosuppressive elements PD-1, on T cells, and PD-L1, on tumor cells. Pancreatic cancers have very little T-cell infiltrate, making them less susceptible to checkpoint blockade than other tumors that are infiltrated by T cells. Therefore, combining BL-8040 with checkpoint blockade is predicted to increase the responsiveness of pancreatic cancer patients to immunotherapy.

### About BL-8040

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and stem cell mobilization. It 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 over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells and immune-cells from the bone marrow, thereby sensitizing cancer cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing cell death (apoptosis) and mobilizing immune-cells. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, T, B and NK cells. 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 focused on oncology and immunology. The Company in-licenses novel compounds, 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 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and has recently initiated a Phase 3 study in stem cell

mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is expected to initiate a first-in-man study in the first half of 2018. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and MSD's KEYTRUDA; and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

For additional information on BioLineRx, please visit the Company's website at [www.bioplinrx.com](http://www.bioplinrx.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 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, 2017. 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.*

KEYTRUDA<sup>®</sup> is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

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