



## BioLineRx Announces Initiation of Immuno-Oncology Phase 2 Study to Investigate Combination of BL-8040 and KEYTRUDA® for Pancreatic Cancer

January 17, 2017

**Study is part of strategic research collaboration between MSD and MD Anderson Cancer Center aimed to evaluate KEYTRUDA in selected GI tumors using various combinations**

TEL AVIV, Israel, January 17, 2017 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the initiation of a second Phase 2a trial investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The study is part of a research collaboration between MSD and MD Anderson Cancer Center.

The open-label, single center, single-arm Phase 2a study aims to evaluate the potential of BL-8040 in combination with KEYTRUDA in pancreatic cancer and focuses on the mechanism-of-action by which both drugs might synergize. In addition to assessing clinical response, the study includes multiple assessments to evaluate the biological anti-tumor effects induced by the combination.

In August 2016, the Company announced the signing of a collaboration agreement with The University of Texas MD Anderson Cancer Center for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer. The investigator-sponsored study is part of a strategic, immuno-oncology, clinical research collaboration between MSD (known as Merck in the US and Canada) and MD Anderson Cancer Center aimed at evaluating Merck's anti-PD-1 therapy, KEYTRUDA, in combination with various treatments and novel drugs.

Philip Serlin, Chief Executive Officer of BioLineRx, said, "This is the second Phase 2 immuno-oncology trial taking place to investigate the combination of BL-8040 and KEYTRUDA for the treatment of pancreatic cancer. In September 2016, we announced the initiation of the COMBAT study, our first Phase 2a study for evaluating the clinical efficacy of BL-8040 in combination with KEYTRUDA, also for the treatment of patients with pancreatic cancer. The COMBAT study, which is being conducted by BioLineRx under a collaboration agreement between BioLineRx and MSD is also currently recruiting patients. We believe that the trial announced today will support the COMBAT study and deepen our understanding of the mechanism-of-action of the combination treatment."

"We also believe that the combination of BL-8040 with KEYTRUDA has the potential to expand the benefit of immunotherapy to non-respondent patients and cancer types currently resistant to immuno-oncology treatments, such as pancreatic cancer. Furthermore, BL-8040's inhibition of CXCR4, which may affect the immunosuppressive tumor micro-environment, is potentially synergistic with immune checkpoint inhibitors in additional oncological indications," added Mr. Serlin.

Dr. David Fogelman, from MD Anderson Cancer Center, the principal investigator of the trial, stated, "We hope that BL-8040 will prime the immune system and increase the anti-tumor activity of Keytruda. We have designed the study to look for evidence of this, both in the tumors themselves and in the patient as a whole. If this combination is successful, we will move pancreatic cancer research forward in a new direction."

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 and to be effective at inducing direct tumor cell death. Additional findings in the field of immuno-oncology suggest that CXCR4 antagonists may be effective in inducing the infiltration of anti-tumor T cells into the tumor. Therefore, when combined with KEYTRUDA, which blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, BL-8040 has the potential to enable activated T cells to better reach tumor cells in the fight against pancreatic cancer.

### About Pancreatic Cancer

Pancreatic cancers of all types are the seventh most common cause of cancer deaths. According to the American Cancer Society, in 2015, nearly 50,000 were diagnosed with pancreatic cancer and an estimated 40,000 will die from the disease. The most common type of pancreatic cancer is pancreatic adenocarcinoma, which accounts for about 85 percent of cases. These [adenocarcinomas](#) start within the part of the pancreas that makes [digestive enzymes](#). There are usually no symptoms in the early stages of the disease and symptoms that are [specific](#) enough to suggest the onset of pancreatic cancer typically do not develop until the disease has reached an advanced stage. The five-year survival rate of pancreatic adenocarcinoma is around seven percent.

### About BL-8040

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. 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 from the bone marrow, thereby sensitizing these cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and 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 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 2a study for

relapsed/refractory AML and is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 2 study in stem cell mobilization for allogeneic transplantation; 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; a collaboration agreement with MSD (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck'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 studies for multiple solid tumor indications and AML.

For additional information on BioLineRx, please visit the Company's website at <http://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 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.*

**Contacts:**

PCG Advisory  
Vivian Cervantes  
Investor Relations  
+1-212-554-5482  
[vivian@pcgadvisory.com](mailto:vivian@pcgadvisory.com)

or

Tsipi Haitovsky  
Public Relations  
+972-52-989892  
[tsipihai5@gmail.com](mailto:tsipihai5@gmail.com)

SOURCE BioLineRx Ltd.