



BioLineRx Announces Regulatory Submissions for Phase 2a Trial of BL-8040 in Combination with KEYTRUDA® (pembrolizumab) for Treatment of Pancreatic Cancer

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- Study expected to commence during Q3 2016 -

TEL AVIV, Israel, June 28, 2016 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the filing of regulatory submissions required to commence a Phase 2a trial for BL-8040 in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with pancreatic cancer. The study is expected to commence shortly after receipt of regulatory approval, anticipated in the third quarter of 2016.

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), MSD's anti-PD-1 therapy, in up to 30 subjects with metastatic pancreatic adenocarcinoma. The study is designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. It is expected to take place in the US, Israel and additional territories.

In January 2016, BioLineRx entered into a collaboration with MSD, known as Merck in the US and Canada, to support a Phase 2 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 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 which may affect both tumor cells and healthy cells, BL-8040 has the potential to enable activated T cells to better reach tumor cells in the fight against pancreatic cancer.

"We are looking forward to commencing this combination study of our lead oncology product and Merck's immune checkpoint inhibitor, which marks the entrance of BL-8040 into the exciting and promising field of cancer immunotherapy," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Over the past few months, we have worked closely with Merck's clinical team on the design and finalization of the study protocol. We believe that the combination of BL-8040 with KEYTRUDA has the potential to expand the benefit of immunotherapy to cancer types currently resistant to immuno-oncology treatments, such as pancreatic cancer, which represent a significant unmet medical need. Furthermore, we view BL-8040's inhibition of CXCR4, which effects a change in the protective tumor micro-environment, as potentially synergistic with immune checkpoint inhibitors in additional oncological indications."

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 7 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, is in the midst of a Phase 2b study as an AML consolidation treatment, and has recently initiated 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, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2a 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.bioglinerx.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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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