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

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BioLineRx Ltd. (NASDAQ/TASE:BLRX) today announced the initiation of a Phase 2a trial investigating BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer.

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 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. The study will be conducted in the US, Israel and additional territories.

In January 2016, BioLineRx entered into an immunotherapy collaboration with MSD, known as Merck in the US and Canada, 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 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.

Philip Serlin, Chief Financial and Operating Officer of BioLineRx, stated, "We are looking forward to conducting this combination study of our lead oncology product and MSD's immune checkpoint inhibitor, which will be the first study of BL-8040 in the exciting and promising field of cancer immunotherapy. 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. To this end, as announced earlier this month, we have entered into a significant cancer immunotherapy collaboration with another global pharma company to support several Phase 1b studies investigating BL-8040 in combination with another immune check point inhibitor in multiple cancer indications. Upon completion of the expected multiple studies, under collaboration with these two world leaders in cancer immunotherapy, each of the parties will have the option to expand the collaboration to include pivotal registration studies," added Mr. Serlin.

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; 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®; and has recently signed 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, 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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