BioLineRx Announces Collaboration with MSD to Investigate the Combination of KEYTRUDA (pembrolizumab) and BL-8040 in Pancreatic Cancer

January 12, 2016

BioLineRx management to hold conference call this morning at 10:00 am EST to further discuss this immunotherapy collaboration

TEL AVIV, Israel, January 12, 2016 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ/TASE: BLRX) today announced 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® (pembrolizumab), MSD's anti-PD-1 therapy, in patients with metastatic pancreatic cancer. The study is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of this combination in patients with metastatic pancreatic adenocarcinoma.

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 migration of anti-tumor T cells into the tumor micro-environment. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA 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. The Phase 2 study will 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.

"We are extremely happy to collaborate with MSD, a pioneer and world leader in cancer immunotherapy. This marks the entrance of BL-8040 into this exciting field, which is already transforming the lives of many cancer patients," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Because certain tumors exhibit only a modest response to existing immunotherapies, we are increasingly seeing clinical studies involving combinations of immuno-oncology agents with other classes of drugs. We are initiating this study with the hope that it will show 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 represents a significant unmet medical need. If this potential can be realized, it will be an extremely important advance in the fight against cancer, as well as a seminal milestone for BioLineRx."

"Today, there is a great opportunity and need to bring forward new scientific breakthroughs for the treatment of pancreatic cancer," said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, MSD Research Laboratories. "Evaluating the potential of combination therapies through strategic collaborations in difficult-to-treat tumor types continues to be an important part of our immuno-oncology clinical development program for KEYTRUDA."

The agreement is between BioLineRx and MSD, through a subsidiary. Per the terms of the agreement, the trial will be sponsored and performed by BioLineRx. The study is planned to commence by mid-2016. Upon completion of the study, or at any earlier point, both parties will have the option to expand the collaboration to include a pivotal registration study. Additional details of the collaboration were not disclosed.

BioLineRx will hold a conference call to discuss the collaboration today, January 12, 2016, at 10:00 am EST. To access the conference call, please dial 1-888-281-1167 from the U.S. or +972-3-918-0610 internationally. The call will also be available via live webcast through BioLineRx's website . A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-326-9310 from the U.S. or +972-3-925-5904 internationally. The replay will be available through January 15, 2016.

About Pancreatic Cancer

There are a number of types of pancreatic cancer. Based on available worldwide numbers, in 2012, pancreatic cancers of all types were 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 is in the midst of a Phase 2 study for relapsed/refractory

AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated 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, 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.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

Various statements in this release concerning 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 actual results, performance or achievements 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" sections of recent annual reports filed by the parties to this release. In addition, any forward-looking statements represent the parties' views only as of the date of this release and should not be relied upon as representing their views as of any subsequent date. The parties do not assume any obligation to update any forward-looking statements unless required by law.

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