



BioLineRx Announces Initiation of Phase 1b/2 Trial for BL-8040 in Gastric Cancer Under Immunotherapy Collaboration

October 18, 2017

Combination trial of BL-8040 and atezolizumab is part of initiative for the development of novel cancer immunotherapy combinations

TEL AVIV, Israel, October 18, 2017 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that Genentech, a member of the Roche Group, has commenced a Phase 1b/2 study for the treatment of gastric cancer with BL-8040 in combination with atezolizumab (TECENTRIQ®), Genentech's anti-PDL1 cancer immunotherapy agent.

Up to 40 patients are planned to be enrolled in this multicenter, randomized, controlled, open-label study to evaluate the clinical response, safety and tolerability, as well as multiple pharmacodynamic parameters, of BL-8040 in combination with atezolizumab. Initially, patients will receive BL-8040 injections as priming monotherapy, after which they will receive both BL-8040 and atezolizumab, and continue with multiple treatment cycles for up to two years or, until disease progression, clinical deterioration or unacceptable toxicity.

The clinical study collaboration between BioLineRx and Genentech is part of MORPHEUS, Roche's novel cancer immunotherapy development platform. MORPHEUS is a phase 1b/2 adaptive platform to develop combinations of cancer immunotherapies more rapidly and efficiently.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "This is the third trial to commence under our collaboration with Genentech for the combination of our CXCR4 inhibitor lead oncology platform and their anti-PDL1 inhibitor, following initiation of a pancreatic cancer study in July and initiation of an AML study in September. We are therefore hopeful that combining atezolizumab with BL-8040 can lead to a significant advancement in the treatment of gastric cancer, and of other solid tumors that are difficult to treat. BL-8040 has shown to induce robust mobilization of immune cells, improve the infiltration of T cells into solid tumors, and affect the immunosuppressive tumor micro-environment. We look forward to the results of this trial and the initiation of an additional combination study under this collaboration, planned for later this year."

This study is being carried out as part of BioLineRx's [cancer immunotherapy collaboration with Genentech](#), which includes several Phase 1b/2 studies investigating BL-8040 in combination with atezolizumab in multiple cancer indications, announced in September 2016.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in clinical trials to be a robust mobilizer of immune cells and to be effective in inducing direct tumor cell death. Additional findings suggest that BL-8040 may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment, as well as improving the infiltration of T cells into solid tumors. Atezolizumab is a humanized monoclonal antibody designed to bind to PD-L1 in tumor cells and tumor infiltrating immune cells and blocks interactions with the PD-1 and B7.1 receptors. Through this interaction, atezolizumab may enable the activation of T cells, whose migration into the tumor may be enhanced by BL-8040.

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 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 cell death (apoptosis). 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 is expected to initiate 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 (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/2 studies for multiple solid tumor indications and AML.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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 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.

Contacts:

PCG Advisory
Vivian Cervantes
Investor Relations
+1-212-554-5482
vivian@pcgadvisory.com

Tsipi Haitovsky
Public Relations
+972-52-989892
tsipihai5@gmail.com

SOURCE BioLineRx Ltd.