



BioLineRx Announces Partial Results of BL-8040 COMBAT Study Accepted for Presentation at ASCO 2018 Gastrointestinal Cancers Symposium

November 20, 2017

Enrollment to COMBAT study has been completed; full topline results expected in H2 2018 as planned

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BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that an abstract with partial results from the monotherapy portion of BL-8040's Phase 2a COMBAT study in pancreatic cancer was accepted for presentation at the [ASCO 2018 Gastrointestinal Cancers Symposium](#), to take place January 18-20, 2018 in San Francisco, CA.

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), an anti-PD-1 therapy marketed by Merck & Co., Inc., (known as MSD outside the United States and Canada), in up to 30 subjects with metastatic pancreatic adenocarcinoma. The study is primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies. In addition, the study will evaluate multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity, for both BL-8040 as a monotherapy, as well as for the combination of BL-8040 and KEYTRUDA. The study is being conducted in the US, Israel and additional territories.

"We are very pleased that the abstract presenting our partial monotherapy results for the COMBAT study were accepted to this important clinical conference. Because of the embargo policy of the conference, we won't be able to share the data by the end of the year, but rather disclose it in January 2018, when the abstracts are released," commented Philip Serlin, Chief Executive Officer of BioLineRx. "As for today, we can report that enrollment of the study has been completed and we are meeting our timelines for conclusion of the study and topline results by the second half of 2018. We are excited about the upcoming topline results in 2018, and continue to fully support our development plan in combination with immune checkpoint inhibitors".

In September 2016, BioLineRx announced the initiation of the COMBAT study, its first Phase 2a study for evaluating the clinical efficacy of BL-8040 in combination with KEYTRUDA, for the treatment of patients with metastatic pancreatic cancer who relapse to previous therapies. The COMBAT study is being conducted by BioLineRx under a collaboration agreement between BioLineRx and MSD, through a subsidiary, 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 tumor cells survival, BL-8040 has the potential to enable activated larger amount of T cells to better reach tumor cells in the fight against pancreatic cancer.

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 and immune-cells from the bone marrow, thereby sensitizing cancer cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing cell death (apoptosis) and mobilizing immune-cells. 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 (tradename of Merck & Co., Inc.), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and MSD'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.

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.

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

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