



BioLineRx Presents Preclinical Data From Triple Combination of BL-8040, Anti PD-1 and Chemotherapy Demonstrating Significant Reduction in Pancreatic Tumor Growth and Favorable Changes in Tumor Microenvironment

November 5, 2019 1:00 PM IST

- Results are being presented at SITC 2019 -

TEL AVIV, Israel, Nov. 5, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today positive preclinical results further elucidating the mechanism of action of BL-8040 in combination with an anti PD-1 and chemotherapy. The results, summarized in a poster entitled, "Combination of BL-8040, anti PD-1 and chemotherapy significantly reduced pancreatic tumor growth and changed the balance between CD4+/FOXP3+ cells and CD8+ cells in the tumor", will be presented on November 8, 2019 at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting in National Harbor, Maryland.

"The results seen in this preclinical pancreatic cancer study support our hypothesis that the triple combination of BL-8040, anti-PD-1 and chemotherapy helps combat this difficult to treat cancer," said Philip Serlin, Chief Executive Officer of BioLineRx. "These preclinical data from the triple combination study support the mechanism of action of BL-8040 demonstrated in earlier clinical data from the dual combination of BL-8040 and pembrolizumab, showing a reduction in immuno-suppressive cells, accompanied by an increase in activated effector CD8+ T cells. We believe the ability of BL-8040 to modulate the tumor microenvironment allows for better activation of immune effector cells when combined with chemotherapy and immunotherapy. We are very hopeful that this anti-tumor activity will be confirmed in humans as we eagerly await results from the triple combination arm of our COMBAT/KEYNOTE-202 Phase 2 study of BL-8040, KEYTRUDA[®] and chemotherapy in metastatic pancreatic cancer, which we expect to report by year end."

About the Pre-Clinical Study

The pre-clinical study assessed the effects of BL-8040, anti-PD-1 and chemotherapy (Irinotecan, Fluorouracil and Leucovorin), both alone and in various combinations, on tumor growth and immune cell constitution in a mouse model for pancreatic cancer.

Key findings include:

- The triple combination of BL-8040+anti-PD-1+chemotherapy had a significantly better effect on tumor growth compared to chemotherapy alone or any dual combination with chemotherapy.
- The triple combination of BL-8040+anti-PD-1+chemotherapy showed the best effect in modulation of the tumor microenvironment, resulting in reduction in immunosuppressive cells, and accompanied by increase of activated T effector cells.

About BL-8040

BL-8040 is a short synthetic peptide that functions as a high-affinity best-in-class antagonist for CXCR4, a chemokine receptor over-expressed in many human cancers. CXCR4 has been shown to be correlated with poor prognosis, and plays a key role in tumor growth, invasion, angiogenesis, metastasis and therapeutic resistance. CXCR4 is also directly involved in the homing and retention of hematopoietic stem cells (HSCs) and various hematological malignant cells in the bone marrow.

In a number of clinical and preclinical studies, BL-8040 has shown a critical role in immune cell trafficking, tumor infiltration by immune effector T cells and reduction in immunosuppressive cells within the tumor niche, turning "cold" tumors, such as pancreatic cancer, into "hot" tumors (i.e., sensitizing them to immune check point inhibitors). BL-8040-mediated inhibition of the CXCR4-CXCL12 (SDF-1) axis has also shown robust mobilization of HSCs for transplantation in hematological malignancies.

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 multiple oncology indications. The Company's lead program, BL-8040, is a cancer therapy platform currently being evaluated in a Phase 2a study in pancreatic cancer in combination with KEYTRUDA[®] and chemotherapy under a collaboration agreement with MSD. BL-8040 is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous hematopoietic cell transplantation. In addition, the Company has an ongoing collaboration agreement with Genentech, a member of the Roche Group, evaluating BL-8040 in combination with Genentech's atezolizumab in two Phase 1b/2 solid tumor studies.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being evaluated in a Phase 1/2a study.

For additional information on BioLineRx, please visit the Company's website at www.bioplinrx.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 28, 2019. 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.

Contact:

Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsipihai5@gmail.com

 View original content: <http://www.prnewswire.com/news-releases/biolinerx-presents-preclinical-data-from-triple-combination-of-bl-8040-anti-pd-1-and-chemotherapy-demonstrating-significant-reduction-in-pancreatic-tumor-growth-and-favorable-changes-in-tumor-microenvironment-300951519.html>

SOURCE BioLineRx Ltd.