BioLineRx Announces Initiation of Phase 2 Clinical Trial in First-Line Metastatic Pancreatic Cancer

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- Investigator-initiated Phase 2 study, led by Columbia University, to evaluate Motixafortide in combination with LIBTAYO® and chemotherapy in first-line metastatic pancreatic ductal adenocarcinoma -

TEL AVIV, Israel, Oct. 29, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical Company focused on oncology, today announced that the Company's lead drug candidate, the CXCR4-inhibitor Motixafortide, will be tested in combination with the anti-PD-1 cemiplimab (LIBTAYO®) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line metastatic pancreatic ductal adenocarcinoma (PDAC).

This investigator-initiated Phase 2 study, led by Columbia University, will initially enroll 10-12 PDAC patients, and will be expanded to a total of 40 patients following an evaluation of the initial 10-12 patients based on pre-defined criteria. The primary endpoint of the study is the overall response rate (ORR). Secondary endpoints include safety and tolerability, progression free survival (PFS), duration of clinical benefit (DCR) and overall survival (OS). Data from the study is anticipated in mid-2022.

"Chemotherapy is the current standard of care for patients with metastatic PDAC, however the rates of response and survival remain very low. In addition, although immunotherapy has resulted in a paradigm shift in the treatment of a number of solid tumors, trials with immune checkpoint blockade in PDAC have been disappointing," stated Dr. Gulam Manji, Assistant Professor of Medicine and Director of Pancreas Medical Oncology and Translational Research at Columbia University Vagelos College of Physicians and Surgeons, and lead investigator. "Over several years of pre-clinical research, we have found that combining a CXCR4 inhibitor with immunotherapy and chemotherapy shows promising results in a mouse model of pancreatic cancer. In this regard, Motixafortide, with its high affinity and long receptor occupancy, together with the encouraging preliminary results published from the COMBAT trial, makes it an attractive candidate for a combination therapy with anti-PD-1 and chemotherapy. We look forward to initiating the first clinical trial to treat patients in first-line metastatic PDAC with this promising treatment regimen."

"We are excited to collaborate with Dr. Manji on this trial, which will further assess the utility of Motixafortide as the backbone of a potentially promising combination therapy in this challenging cancer indication," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The results reported to date in our ongoing COMBAT-KEYNOTE-202 study, which is evaluating Motixafortide in combination with KEYTRUDA® and chemotherapy in second-line metastatic PDAC, demonstrate an encouraging anti-tumor effect when compared to historical data. We are hopeful that we can replicate these improved responses in this first-line study and look forward to data in mid-2022. This is yet another potentially value-creating milestone that further validates Motixafortide's potential ability to treat a range of cancers across all stages of disease."

About Motixafortide in Cancer Immunotherapy

Motixafortide is targeting CXCR4, a chemokine receptor and a well validated therapeutic target that is over-expressed in many human cancers including PDAC. CXCR4 plays a key role in tumor growth, invasion, angiogenesis, metastasis and therapeutic resistance, and CXCR4 overexpression has been shown to be correlated with poor prognosis.

Motixafortide is a short synthetic peptide used as a platform for cancer immunotherapy with unique features allowing it to function as a best-in-class antagonist of CXCR4. It shows high-affinity, long receptor occupancy and acts as an inverse agonist.

In a number of clinical and preclinical studies, Motixafortide has been shown to affect multiple modes of action in "cold" tumors, including immune cell trafficking, tumor infiltration by immune effector T cells, and reduction in immunosuppressive cells (such as MDSCs) within the tumor niche, turning "cold" tumors, such as pancreatic cancer, into "hot" (i.e., sensitizing them to immune checkpoint inhibitors and chemotherapy).

About Pancreatic Cancer

Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. Its incidence rate in the US is estimated at 3.2% of new cancer cases. In 2018, approximately 450,000 individuals globally were diagnosed with this condition, 55,000 of them in the US; and the incidence of pancreatic cancer is expected to continue to increase. Symptoms are usually non-specific and as a result, pancreatic cancer is often not diagnosed until it reaches an advanced stage. Surgical resection does not offer adequate treatment since only 20% of patients have resectable tumors at the time of diagnosis. Even among patients who undergo resection for pancreatic cancer and have tumor-free margins, the five-year survival rate is only 10%-25%. The overall five-year survival rate among pancreatic cancer patients is 10%, which constitutes the highest mortality rate among solid tumor malignancies. The overall median survival is less than one year from diagnosis, highlighting the need for the development of new therapeutic options.

Despite advances in chemotherapeutics and immunotherapy, increases in median and overall survival rates in pancreatic cancer have been modest. Pancreatic cancer remains an area of unmet medical need, with no new approved therapies since the approval of nab-paclitaxel (Abraxane®) in combination with gemcitabine for first-line treatment in 2013 and Onivyde® in combination with fluorouracil and leucovorin for second-line treatment in 2015. The limited clinical benefits demonstrated by these existing standard treatment options reinforce the need for additional approaches.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform currently being evaluated in a Phase 2a study for the treatment of

pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. Motixafortide is also being evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation and a Phase 2b study in consolidation AML.

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

For additional information on BioLineRx, please visit the Company's website at 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. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the coronavirus outbreak; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 12, 2020. 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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