BioLineRx Announces Initiation of Randomized Phase 2 Clinical Trial in First Line Metastatic Pancreatic Cancer Based on Preliminary Data from Single-Arm Pilot Phase; Combination Trial Includes Investigational Candidate Motixafortide

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TEL AVIV, Israel, July 17, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases, today announced the initiation of a randomized, investigator-initiated Phase 2 clinical trial in first line metastatic pancreatic cancer based on preliminary data from the single-arm pilot phase. The combination drug trial includes the investigational candidate motixafortide. Sponsored by Columbia University, the amended study will modify a single-arm trial whose original design called for expansion to an additional 30 patients if data from a pilot phase of 10 patients was encouraging (defined as ≥3 patients with partial response by RECIST criteria). The amended randomized study will compare combination treatment with the Company's CXCR4 inhibitor (motixafortide), a PD-1 inhibitor (cemiplimab), and chemotherapy (gemcitabine, nab-paclitaxel) to chemotherapy alone in a larger number of patients (n= 102).

A poster of the amended clinical trial design was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, held June 2-6 in Chicago, Illinois (see abstract).

"Metastatic pancreatic cancer is a uniformly fatal disease for which current treatments result in limited benefits," said Tami Rachmilewitz, MD, Chief Medical Officer at BioLineRx. "Unfortunately, newer immunotherapy approaches, while beneficial against other solid tumor types, have had limited efficacy in pancreatic cancer due to immunosuppressive pathways. Combining checkpoint inhibitors, chemotherapy, and a CXCR4 inhibitor has shown promise in earlier preclinical and clinical studies, including an earlier single arm study using motixafortide as the CXCR4 inhibitor (COMBAT/KEYNOTE-202) in patients receiving second line treatment for pancreatic cancer, and we are very encouraged by the results seen in the initial pilot phase of the study in patients receiving first line treatment. We look forward to continuing the clinical research of this treatment regimen in this randomized trial."

"Working with our collaborators, we are excited to be advancing the clinical development of motixafortide in pancreatic cancer and look forward to the presentation of data from the pilot phase of the randomized trial later this year," said Philip Serlin, Chief Executive Officer of BioLineRx. "This is an important area of growth for the company, alongside the potential approval and U.S. commercialization of motixafortide this year in stem cell mobilization for autologous transplantation in multiple myeloma."

Data from the pilot stage of the Phase 2 study is planned for submission to a congress later this year. The primary endpoint of the randomized trial is progression free survival (PFS). Secondary objectives include safety, response rate, disease control rate, duration of clinical benefit and overall survival.

The U.S. Food and Drug Administration has accepted the company's New Drug Application for motixafortide in stem cell mobilization for autologous transplantation in multiple myeloma and assigned the NDA a PDUFA date of September 9, 2023.

About Pancreatic Cancer
Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. In the United States in 2023, an estimated 64,050 adults will be diagnosed with the disease, which accounts for approximately 3% of all cancers in the U.S. and about 7% of all cancer deaths. Worldwide, an estimated 495,773 people were diagnosed with the disease in 2020. In the U.S., if the cancer is detected at an early stage when surgical removal of the tumor is possible, the 5-year relative survival rate is 44%. About 12% of people are diagnosed at this stage. If the cancer has spread to surrounding tissues or organs, the 5-year relative survival rate is 15%. For the 52% of people who are diagnosed after the cancer has spread to a distant part of the body, the 5-year relative survival rate is 3%.[i] These data highlight the need for the development of new therapeutic options.

About Motixafortide in Cancer Immunotherapy
Motixafortide inhibits CXCR4, a chemokine receptor and a well validated therapeutic target that is over-expressed in many human cancers including pancreatic ductal adenocarcinoma (PDAC). Motixafortide leverages the expression of the CXCR4 receptor on different immune cells and potentiates the immune system against the tumor. Among CXCR4-expressing immune cells, some exhibit anti-tumoral activity, such as effector T cells and some exhibit pro-tumoral activity and support tumor growth. By blocking the CXCR4 receptor, motixafortide was shown in a Phase 2 study in pancreatic cancer patients to enhance anti-tumoral activity and to ameliorate the pro-tumoral activities by modulating the effector/suppressor cell ratio towards a proinflammatory profile.

About BioLineRx
BioLineRx Ltd. is a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases. The company is advancing a pipeline of investigational medicines for patients with multiple myeloma, sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., BioLineRx is driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

Forward Looking Statement
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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, our planned and ongoing clinical trials, including the plans and objectives of management for future operations and expectations and commercial potential of motixafortide. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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, including BioLineRx's ability to secure adequate and viable pricing and reimbursement coverage of any marketed product; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate and academic collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation or characterization 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 and ability to access sufficient 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 unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; 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 22, 2023. 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.

[i] ASCO Cancer.Net. Cancer.Net Editorial Board Approval March 2023.

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