BioLineRx Announces Encouraging Data from Pilot Phase of Phase 2 Combination Clinical Trial with Motixafortide in First-Line Pancreatic Cancer (PDAC)

September 28, 2023 11:00 AM IDT

- 6 of 11 Patients in the Pilot Phase Experienced a Partial Response, with 4 Confirmed; One Patient Experienced Resolution of the Hepatic Metastatic Lesion -

- Data Presented at AACR Special Conference on Pancreatic Cancer -

- Multi-Center, Randomized Phase 2 Study Currently Enrolling -

TEL AVIV, Israel, Sept. 28, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced encouraging data from the single-arm pilot phase of the investigator-initiated CheMo4METPANC Phase 2 combination clinical trial evaluating the company's CXCR4 inhibitor motixafortide, the PD-1 inhibitor cemiplimab, and standard of care chemotherapies gemcitabine and nab-paclitaxel, versus gemcitabine and nab-paclitaxel alone, in first-line pancreatic cancer (PDAC).

The data were published in an online abstract as part of the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer taking place in Boston, Massachusetts from September 27-30, 2023. An oral presentation of the data will take place later today, September 28, 2023.

The pilot phase of the Phase 2 study enrolled 11 patients with metastatic pancreatic cancer. As of May 2023, 6 patients (55%) experienced a partial response (PR) of which 4 (36%) were confirmed PRs with one patient experiencing resolution of the hepatic (liver) metastatic lesion. Three patients (27%) experienced stable disease, resulting in a disease control rate of 82%. These findings compare favorably to historic partial response and disease control rates of 23% and 48%, respectively, reported with the current standard of care, the chemotherapy combination gemcitabine and nab-paclitaxel.

"These initial data from the pilot phase of this ongoing Phase 2 study give us hope that motixafortide could potentially serve as the backbone of a new treatment regimen for PDAC, which is among the most difficult cancers to treat," said Philip Serlin, Chief Executive Officer of BioLineRx Ltd. "We are deeply committed to this important collaboration with Columbia University investigators and eagerly look forward to the data from the randomized phase of the trial."

Based on these pilot data, earlier this year, the CheMo4METPANC Phase 2 trial was amended to become a randomized study, with planned enrollment increasing from 30 to 102 patients. The trial, sponsored by Columbia University, is the first large, multi-center, randomized study evaluating motixafortide with a PD-1 inhibitor and first-line PDAC chemotherapies. 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).

Pancreatic ductal adenocarcinoma (PDAC) is the most common type of pancreatic cancer and is expected to be the second leading cause of cancer-related death in the U.S. by 2023. Because it is typically diagnosed at later stages, greater than 80 percent of pancreatic cancer is inoperable. Most pancreatic cancer is incurable and unfortunately newer immunotherapy approaches, while beneficial against other solid tumor types, have had limited efficacy in pancreatic cancer due to immunosuppressive pathways.

An earlier single-arm, Phase 2a clinical trial (COMBAT/KEYNOTE-202) and pre-clinical studies evaluating motixafortide in combination with PD-1 immunotherapies and chemotherapies in PDAC have been promising, suggesting the ability of motixafortide to support an immune response.

Presentation at AACR Special Conference in Cancer Research: Pancreatic Cancer

Westin Copley Place, Boston Massachusetts

Plenary Session Details

Title: CheMo4METPANC: Combination Chemotherapy (gemcitabine and nab-paclitaxel), chemokine (C-X-C) Motif receptor 4 inhibitor (motixafortide), and immune checkpoint blockade (cemiplimab) in METastatic treatment-naïve PANCreatic adenocarcinoma

Presenter: Gulam A. Manji, MD, PhD, Columbia University Irving Medical Center/New York Presbyterian, New York, N.Y.

Session: Plenary Session 3: Clinical Updates

Date: Thursday, September 28, 2023

Time: 2:30-4:40 pm EDT

About CheMo4METPANC Phase 2 Clinical Trial

The multi-center CheMo4METPANC Phase 2 clinical trial is a randomized, investigator-initiated clinical trial in first line metastatic pancreatic cancer. Sponsored by Columbia University, the study is evaluating the combination of CXCR4 inhibitor motixafortide, PD-1 inhibitor cemiplimab, and standard of care chemotherapies gemcitabine and nab-paclitaxel, versus gemcitabine and nab-paclitaxel, alone in 102 patients. The trial's primary endpoint is progression free survival (PFS). Secondary objectives include safety, response rate, disease control rate, duration of clinical benefit and overall survival.

About Pancreatic Cancer

Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. In the United States in 2023, an estimated 64,000 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 496,000

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 initially 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 patients who are initially diagnosed with metastatic cancer, the 5-year relative survival rate is 3%.[i] In particular, hepatic (liver) metastases are a critical risk factor driving poor prognoses for patients with metastatic PDAC. 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. (NASDAQ/TASE: BLRX) is a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company's first approved product is APHEXDA™ (motixafortide) with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma. BioLineRx is advancing a pipeline of investigational medicines for patients with sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., the company 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, the potential benefits of APHEXDA, the timing and execution of the launch of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of motixafortide, as well as its potential investigational uses. 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; whether the clinical trial results for APHEXDA will be predictive of real-world results; 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, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; 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 and ability to access sufficient additional financing, including any unexpected costs or delays in the commercial launch of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above. 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.

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

View original content:https://www.prnewswire.com/news-releases/biolinerx-announces-encouraging-data-from-pilot-phase-of-phase-2-combination-clinical-trial-with-motixafortide-in-first-line-pancreatic-cancer-pdac-301941126.html

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