BioLineRx Announces Acceptance of Oral Presentation on Pilot Phase Data from Phase 2 Combination Clinical Trial with Motixafortide in First-Line PDAC at AACR Special Conference on Pancreatic Cancer

September 19, 2023 11:00 AM IDT

Abstracts to be Published on American Association of Cancer Research (AACR)
Virtual Meeting Platform at 5:30 pm EDT on Wednesday, September 27, 2023

Oral Presentation on Thursday, September 28, 2023, in Boston, Massachusetts

TEL AVIV, Israel, Sept. 19, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that pilot phase data from an investigator-initiated, open-label, multicenter Phase 2 clinical trial with motixafortide in first-line pancreatic ductal adenocarcinoma (PDAC) will be presented at the American Association for Cancer Research (AACR) Special Conference on Pancreatic Cancer taking place in Boston, Massachusetts, September 27-30, 2023. The Phase 2 clinical trial is designed to evaluate the company's CXCR4 inhibitor motixafortide in combination with 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).

Sponsored by Columbia University, the single-arm pilot phase of the Phase 2 trial focused on the safety of the drug combination. Additionally, based on the original protocol, if ≥3 of the planned 10 patients within the pilot phase experienced a partial response (PR) by RECIST criteria within 16 weeks, the combination would be considered promising and an expansion cohort of an additional 30 patients would be initiated for enrollment. Earlier this year, following a review of the pilot phase data, the trial was amended to become a randomized study, with planned enrollment increasing from 30 to 102 patients. 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).

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 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 people who are initially diagnosed with metastatic cancer, 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. (NASDAQ: BLRX) (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 commercial 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.

Contacts:

United States
John Lacey
BioLineRx
ir@biolinerx.com

Israel
Moran Meir
LifeSci Advisors, LLC
moran@lifesciadvisors.com

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

View original content:https://www.prnewswire.com/news-releases/biolinerx-announces-acceptance-of-oral-presentation-on-pilot-phase-data-from-phase-2-combination-clinical-trial-with-motixafortide-in-first-line-pdac-at-aacr-special-conference-on-pancreatic-cancer-301931109.html

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