



BioLineRx Announces First Patient Dosed in Randomized Phase 2 Combination Clinical Trial Evaluating Motixafortide in First-Line Pancreatic Cancer (PDAC)

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- Conducted in Collaboration with Columbia University, the CheMo4METPANC Phase 2 trial is the first large, multi-center, randomized study evaluating motixafortide with a PD-1 inhibitor and first-line PDAC chemotherapies compared to chemo alone -

- Gulam Manji, MD, PhD, of Columbia University to present encore pilot phase data at the Immuno-Oncology (IO) 360° Summit on February 29 -

TEL AVIV, Israel, Feb. 28, 2024 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that the first patient has been dosed in the randomized 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 investigator-initiated trial is being conducted in collaboration with Columbia University and is the first large, multi-center, randomized study evaluating motixafortide with a PD-1 inhibitor and first-line PDAC chemotherapies.

"Pancreatic ductal adenocarcinoma (PDAC) has had limited responses to traditional immunotherapy, resulting in a poor prognosis for patients and an urgent need for new treatment approaches," said Philip Serlin, Chief Executive Officer of BioLineRx. "We are encouraged by our early pilot data and look forward to continuing to advance the expanded, randomized Phase 2 CheMo4METPANC trial for patients living with this cancer."

Findings from the single-arm pilot phase of the CheMo4METPANC trial will be shared by Dr. Manji at the 10th Annual Immuno-Oncology (IO) 360° Summit in Brooklyn, New York on Thursday, February 29, 2024. The findings were previously presented during an oral presentation at the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer in Boston, Massachusetts, September 28, 2023. As of July 2023, 7 of the 11 patients (64%) in the pilot phase experienced a partial response (PR) of which 5 (45%) were confirmed PRs at the time of the data cut; one patient experienced resolution of the hepatic (liver) metastatic lesion; and three patients (27%) experienced stable disease, resulting in a disease control rate of 91%.

Motixafortide, BioLineRx's lead therapeutic candidate, was approved by the U.S. Food & Drug Administration (FDA) in September 2023, in combination with filgrastim (G-CSF), to mobilize hematopoietic stem cells for collection and subsequent autologous transplantation in patients with multiple myeloma, under the brand name APHEXDA®. Motixafortide is also being evaluated in a Phase 1 clinical trial evaluating motixafortide as a monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell (HSC) mobilization for gene therapies in sickle cell disease (SCD).

About CheMo4METPANC Phase 2 Clinical Trial

The multi-center CheMo4METPANC Phase 2 clinical trial ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04543071) Identifier: [NCT04543071](https://clinicaltrials.gov/ct2/show/study/NCT04543071)) is a randomized, investigator-initiated clinical trial in first line metastatic pancreatic cancer. Sponsored by Columbia University, and supported equally by BioLineRx and Regeneron, 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 108 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 2024, an estimated 66,000 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.¹ 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%.² 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: 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 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 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 BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; whether the clinical trial results for APHEXDA will be predictive of real-world results; whether early stage clinical trial results, or pre-clinical results, will be predictive of, or repeatable in, later 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, 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, operationalize 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; the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic, the Russian invasion of Ukraine, the declared war by Israel against Hamas and the military campaigns against Hamas and other terrorist organizations, 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.

1. American Cancer Society. *Key Statistics for Pancreatic Cancer*. Atlanta, Ga: American Cancer Society; 2024.
2. ASCO [Cancer.Net](#). Editorial Board Approval March 2023.

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