BioLineRx Announces New Pilot Phase Data from Phase 2 Combination Trial of Motixafortide in First-Line Pancreatic Cancer (PDAC) to be Presented at ASCO 2025 Annual Meeting

May 30, 2025 11:00 AM IDT

- 4 of 11 PDAC patients in the pilot phase remained progression free at over one year

- Poster presentation on Saturday, May 31st

TEL AVIV, Israel, May 30, 2025 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a development stage biopharmaceutical company pursuing life-changing therapies in oncology and rare disease, today announced that a poster including new data from the single-arm pilot phase of the investigator-initiated, randomized CheMo4METPANC Phase 2 combination clinical trial will be presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30-June 3, 2025 in Chicago, Illinois.

The CheMo4METPANC trial is 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).

Updated results from the pilot phase indicate that four of eleven patients remained progression free after more than one year. Two patients underwent definitive treatment for mPDAC: one had complete resolution of all radiologically detected liver lesions and underwent definitive radiation to the primary pancreatic tumor, and one had a sustained partial response and underwent pancreaticoduodenectomy with pathology demonstrating a complete response. An analysis of pre- and on-treatment biopsies and peripheral blood mononuclear cells (PBMCs) also revealed that CD8+ T-cell tumor infiltration increased across all eleven patients treated with the motixafortide combination. In addition, patients achieving a partial response were found to have higher pre-treatment proportions of CXCL12-producing cancer associated fibroblasts, a potential marker of response.

"The data that continue to emerge from the pilot phase of the CheMo4METPANC Phase 2 study are extremely encouraging, with four of eleven patients remaining progression free after more than one year, as well as two patients that underwent definitive treatment, in what has historically been among the most challenging tumor types to treat," stated Philip Serlin, Chief Executive Officer of BioLineRx Ltd. "Notably, these results further suggest that the combination of motixafortide, cemiplimab and standard-of-care chemotherapy can overcome the immunosuppressive mechanisms of the tumor microenvironment (TME) and increase intratumoral CD8+ T-cell infiltration, resulting in improved patient outcomes. We look forward to results from the ongoing randomized portion of this important study."

The pilot clinical trial of motixafortide, cemiplimab, gemcitabine and nab-paclitaxel (N=11) demonstrated an overall response rate (ORR) of 64% (7/11) and a disease control rate (DCR) of 91% (10/11), compared to historical ORR and DCR of 23% and 48%, respectively, with gemcitabine and nab-paclitaxel. Based on these encouraging results, the CheMo4METPANC Phase 2 trial was amended to become a randomized study, with planned enrollment increasing from 30 to 108 patients. The trial is the first large, multi-center, randomized study evaluating motixafortide with a PD-1 inhibitor and first-line PDAC chemotherapies. The trial is planned to be fully enrolled in 2027, and a prespecified interim analysis is planned for when 40% of PFS events are observed.

Poster Presentation at ASCO 2025
McCormick Place, Chicago, Illinois

Poster Session Details

Primary Track: Gastrointestinal Cancer—Gastroesophageal, Pancreatic and Hepatobiliary

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 Abbas Manji, MD, PhD, Columbia University Herbert Irving Comprehensive Cancer Center
Abstract: 4167
Poster Bd #: 457
Date: May 31, 2025
Time: 9:00am CDT
Location: Hall A

About CheMo4METPANC Phase 2 Clinical Trial
The multi-center CheMo4METPANC Phase 2 clinical trial (ClinicalTrials.gov Identifier: 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/TASE: BLRX) is a biopharmaceutical company pursuing life-changing therapies in oncology and rare disease. 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, which is being developed and commercialized by Ayrmid Ltd. (globally, excluding Asia) and Gloria Biosciences (in Asia). BioLineRx is utilizing its end-to-end expertise in development, regulatory affairs and manufacturing to advance its innovative pipeline and ensure 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 success of the license agreement with Ayrmid and the commercial potential of motixafortide, expectations with regard to clinical trials of motixafortide, the expected cash runway, and BioLineRx's business strategy. 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 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; 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; 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, manage, and maintain corporate collaborations, as well as the ability of BioLineRx's collaborators to execute on their development and commercialization plans; BioLineRx's ability to integrate new therapeutic candidates and new personnel as well as new collaborations; 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; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; BioLineRx's ability to maintain the listing of its ADSs on Nasdaq; and statements as to the impact of the political and security situation in Israel on BioLineRx's business, 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 31, 2025. 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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