BioLineRx Announces Clinical Trial Collaboration with Washington University School of Medicine to Evaluate Motixafortide for CD34+ Hematopoietic Stem Cell Mobilization for Gene Therapies in Sickle Cell Disease

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- Clinical trial part of long-term growth strategy for motixafortide across multiple potential therapeutic areas -

TEL AVIV, Israel, March 6, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced a collaboration with Washington University School of Medicine in St. Louis to advance a Phase 1 clinical trial that will evaluate the safety and feasibility of the Company's lead clinical candidate motixafortide to mobilize CD34+ hematopoietic stem cells (HSCs) for gene therapies in sickle cell disease (SCD), one of the most common genetic diseases globally. Currently available mobilization regimens can carry serious risks and side effects for patients with SCD or may not reliably yield optimal numbers of HSCs for gene therapy.

The clinical trial is part of the Company's long-term growth strategy for motixafortide across multiple therapeutic areas, including a potential future indication as a stem cell mobilization agent to support gene therapy development.

"Autologous hematopoietic stem cell-based gene therapies now offer curative potential for patients with SCD, but they are dependent upon the collection of significant quantities of stem cells, including early progenitor stem cells," said John DiPersio, MD, PhD, Professor of Medicine and Director of the Center for Gene and Cellular Immunotherapy at Washington University School of Medicine, and principal investigator of the trial. "The common mobilization agent G-CSF is contraindicated in patients with sickle cell disease, significantly limiting their stem cell mobilization options. The development of novel mobilization regimens has the potential to overcome this unmet need for patients."

"We are excited to be advancing this important collaboration, which has the potential to ultimately support sickle cell disease gene therapy for patients," said Tami Rachmilewitz, MD, Chief Medical Officer at BioLineRx. "Motixafortide is being developed across multiple therapeutic areas, including stem cell mobilization for multiple myeloma, treatment of pancreatic cancer, and now in support of stem cell mobilization for gene therapy development for genetic disorders, which, we believe, demonstrates its broad potential."

The proof-of-concept trial, which will study motixafortide as a single agent and in combination with natalizumab, will assess the safety and tolerability of the two regimens as mobilization agents of CD34+ hematopoietic stem cells in patients with SCD. The study is anticipated to begin enrollment in the second half of 2023.

About the Clinical Trial of Motixafortide in Sickle Cell Disease (SCD)

The trial is a safety and feasibility study to evaluate motixafortide (CXCR4 inhibitor) as monotherapy and in combination with natalizumab (VLA-4 inhibitor) as novel regimens to mobilize CD34+ hematopoietic stem cells for gene therapies in SCD. The study will enroll five adults with a diagnosis of SCD who are receiving automated red blood cell exchanges via apheresis. The trial's primary objective is to assess the safety and tolerability of motixafortide alone and the combination of motixafortide + natalizumab in SCD patients, defined by dose-limiting toxicities. Secondary objectives include determining the number of CD34+ hematopoietic stem and progenitor cells (HSPCs) mobilized via leukapheresis; and determining the kinetics of CD34+ HSPCs mobilization to peripheral blood in response to motixafortide alone and motixafortide + natalizumab in SCD patients.

About Sickle Cell Disease

Sickle cell disease (SCD) is one of the most common genetic diseases globally, affecting millions of people throughout the world and disproportionately impacting persons of color. Sickle cell disease arises from mutations in the hemoglobin gene, ultimately leading to the production of abnormally shaped (sickle) red blood cells that tend to stick to blood vessels causing their occlusion. The clinical manifestations of SCD include anemia and blood vessel occlusion which can lead to both acute and chronic pain, as well as tissue ischemia across multiple organ systems (e.g., stroke, heart attack, respiratory failure), ultimately compromising end organ function. The cumulative impact of these complications significantly impacts morbidity and mortality for patients with SCD.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation for multiple myeloma patients, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., and has had its NDA submission accepted by the FDA with an assigned PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first line PDAC therapy. In addition, a randomized phase 2b study with 200 patients in combination with PD1 and chemotherapy as a first line PDAC therapy is expected to initiate in 2023. BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors. A first-in-human Phase 1/2a study of AGI-134 met its primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers. For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

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 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; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; 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; 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 16, 2022. 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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