BioLineRx Announces Clinical Trial Agreement with St. Jude Children's Research Hospital, Inc. to Evaluate Motixafortide for CD34+ Hematopoietic Stem Cell (HSC) Mobilization For Gene Therapy Applications in Sickle Cell Disease (SCD)

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- Investigator-initiated study includes leading researchers in SCD gene therapy clinical development from St. Jude Children's Research Hospital, Inc. *and two other clinical sites -*

- New trial to expand ongoing clinical research of motixafortide for mobilization of HSCs in patients with SCD -

TEL AVIV, Israel, May 30, 2024 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced a multi-center Phase 1 clinical trial sponsored by St. Jude Children's Research Hospital, Inc. to evaluate motixafortide for the mobilization of CD34+ hematopoietic stem cells (HSCs) used in the development of gene therapies for patients with sickle cell disease (SCD). Investigators in the trial from St. Jude Children's Research Hospital, Inc. and two other clinical sites have extensive SCD gene therapy clinical development experience and are recognized leaders in the field.

Hematopoietic stem cell transplantation after genetic modification is potentially curative for patients with SCD. Significant quantities of HSCs (minimum 16.5-20 million cells/kg) are required for genetic manipulation and transplant success, however, the most commonly used drug for collection of stem cells, granulocyte colony-stimulating factor (G-CSF), is contraindicated in patients with SCD. Peripheral blood mobilization of stem cells using the mobilization agent plerixafor is the current strategy to collect HSCs for SCD gene therapies, however limitations exist including the need for multiple collection cycles to achieve the necessary HSC yields. For some, gene therapy may be prohibitive by the failure to obtain adequate numbers of HSCs.

"The recent FDA approvals of two gene therapies for sickle cell disease in the U.S. is an exciting development for the sickle cell community," said Ella Sorani, PhD, Chief Development Officer at BioLineRx. "Through this new trial with St. Jude, and our ongoing collaboration with investigators at Washington University School of Medicine in St. Louis, we are excited to be working with leaders in gene therapy and stem cell mobilization to evaluate potential new mobilization options for patients with SCD."

Enrollment in the St. Jude Children's Research Hospital, Inc. study is expected to begin in the next few months. Initial data from the Washington University School of Medicine in St. Louis sponsored clinical trial (ClinicalTrials.gov Identifier: NCT05618301) is anticipated in the second half of 2024.

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 HSCs for collection and subsequent autologous transplantation in patients with multiple myeloma, under the brand name APHEXDA®.

About SCDSTEMM Clinical Trial with St. Jude Children's Research Hospital Inc.

The SCDSTEMM (Sickle Cell Disease Stem Cell Mobilization and Apheresis Using Motixafortide) Phase 1 clinical trial is an open-label, multi-center study evaluating the safety, tolerability, and feasibility of single-agent motixafortide (CXCR4 inhibitor) for the mobilization and collection of CD34+ HSCs in 12 patients (aged 18 and older) with SCD. The trial's primary objective is to assess the safety and tolerability of motixafortide in SCD patients, as determined by the incidence of adverse events. Secondary objectives include understanding CD34+ kinetics after motixafortide administration in patients with SCD and determining the number of CD34+ HSCs collected via leukapheresis. The study is designed in two parts: Part A (N=6) will evaluate single dose motixafortide mobilization followed by one apheresis session; Part B (N=6) will evaluate daily motixafortide administration over a two-day mobilization and apheresis regimen. Additional objectives include phenotype and cell function characterization, as well as assessment of the gene modifying potential and senescence of CD34+ cells.

About 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. SCD arises from mutations in the hemoglobin gene, ultimately leading to the production of abnormally shaped (sickle) red blood cells. 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., brain, lungs, heart, kidneys, spleen, liver, bones), 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 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, expectations with regard to clinical trials of motixafortide. 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; 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; 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, 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 26, 2024. 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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