BioLineRx Announces Additional Positive Results from Pharmacoeconomic Study Comparing Motixafortide + G-CSF to Plerixafor + G-CSF in Stem Cell Mobilization

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- Results demonstrate highly significant cost benefits of using Motixafortide in combination with G-CSF, versus plerixafor with G-CSF, for stem cell mobilization in all multiple myeloma patients undergoing autologous stem cell transplantation

- Results reinforce and enhance the economic benefit seen in earlier evaluation of Motixafortide in combination with G-CSF, versus G-CSF alone, reported in Oct 2021

TEL AVIV, Israel, March 3, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today announced additional positive results from a follow-on pharmacoeconomic study that was performed based on data from the Company's successful Phase 3 GENESIS trial. This new study indirectly evaluated the cost-effectiveness of using the investigational drug Motixafortide as a primary stem cell mobilization (SCM) agent in combination with granulocyte colony stimulating factor (G-CSF), against plerixafor in combination with G-CSF, in multiple myeloma patients undergoing autologous stem cell transplantation (ASCT). The results from the follow-on study, which was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA, reinforce and enhance the economic benefits previously seen in the main study evaluating Motixafortide in combination with G-CSF, versus G-CSF alone, as part of the GENESIS study, on which the Company reported in October 2021.

The additional study results show that Motixafortide in combination with G-CSF, versus plerixafor in combination with G-CSF, demonstrates a statistically significant decrease in health resource utilization (HRU) during the ASCT process. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show quality-adjusted-life-year (QALY) benefits and net cost savings of ~$30,000 (not including the cost of Motixafortide), versus plerixafor plus G-CSF. The study findings strengthen the assessment that the use of Motixafortide in combination with G-CSF, as the potential new standard of care in mobilization for ASCT, would be a cost-effective option in the US, based on accepted willingness-to-pay (WTP) values for healthcare payers.

"The results of this pharmacoeconomic study have now demonstrated significant net cost savings of using Motixafortide plus G-CSF, versus both plerixafor plus G-CSF and versus G-CSF alone," stated Philip Serlin, Chief Executive Officer of BioLineRx. "These savings relative to available stem cell mobilization options, along with the vastly improved clinical outcomes demonstrated by our GENESIS Phase 3 study showing that nearly 90% of patients collected an optimal number of cells for transplantation following a single administration of Motixafortide and in only one apheresis session, further strengthen the commercial case for Motixafortide in combination with G-CSF in stem cell mobilization.

"This stronger performance and efficiency are particularly crucial when considering the trend toward more aggressive induction treatment protocols that leave patients needing more effective mobilization options. Accordingly, we believe our product has the potential to become the new standard of care for all multiple myeloma patients undergoing autologous stem cell transplantation, and potentially for other indications as well, addressing a market with estimated potential revenues of more than $360 million in the US alone. Our team is working diligently to bring this product to patients, and we now expect to file an NDA submission in mid-2022. If approved, Motixafortide would represent the first significant advancement in stem cell mobilization since the approval of plerixafor in 2008, and we intend to maximize the value of this opportunity for shareholders," Mr. Serlin concluded.

About the Follow-on Pharmacoeconomic Study

The follow-on study was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA, as a supplemental analysis to the original pharmacoeconomic study announced in October 2021 comparing motixafortide + G-CSF to G-CSF alone. For this follow-on study, an adjusted indirect comparison was undertaken, using data from the relevant phase 3 trials, to compare motixafortide + G-CSF with plerixafor + G-CSF, in stem cell mobilization in patients with multiple myeloma. This included finding and extracting efficacy data for both Motixafortide (from GENESIS patient-level data) and plerixafor (aggregate data from literature), estimating plerixafor efficacy as if it had been one arm of the GENESIS trial (Bucher method), and implementing the results in the cost-effectiveness model.

About the GENESIS Phase 3 Trial

The GENESIS Phase 3 trial (NCT03246529) was initiated in December 2017. GENESIS was a randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability and efficacy of Motixafortide and G-CSF, compared to placebo and G-CSF, for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients. The primary objective of the study was to demonstrate that only one dose of Motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize ≥ 6 million CD34+ cells in up to two apheresis sessions. Additional objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters. The study successfully met all primary and secondary endpoints with an exceptionally high level of statistical significance ($p<0.0001$), including approximately 90% of patients who mobilized the target number of cells for transplantation with only one administration of Motixafortide and in only one apheresis session.

About Stem Cell Mobilization for Autologous Stem Cell Transplantation

Autologous stem cell transplantation (ASCT) is part of the standard treatment paradigm for a number of blood cancers, including multiple myeloma, non-Hodgkin's lymphoma and other lymphomas. In eligible patients, ASCT is performed after initial (induction) therapy, and, in most cases, requires consecutive-day clinic visits for the mobilization and apheresis (harvesting) phases, and full hospitalization for the conditioning chemotherapy and transplantation phases until engraftment. The associated burden is therefore significant – patients experience clinically relevant deteriorations in their quality of life during ASCT, and healthcare resource use throughout the ASCT phases is particularly intense. Therefore, new interventions impacting the ASCT process have the potential for relieving some of the clinical burden for transplanted patients, the logistical burden for the apheresis units, and the financial burden for healthcare providers and payers.

Described simply, ASCT consists of: (1) mobilizing the patient's own stem cells from his/ her bone marrow to the peripheral blood for removing

(harvesting) via an apheresis procedure; (2) freezing and storing the harvested cells until they are needed for transplantation; (3) providing a conditioning treatment, such as high-dose chemotherapy or radiation, to kill the remaining cancer cells the day before transplant; and (4) infusing the stored stem cells back to the patient intravenously via a catheter.

To mobilize the patient's stem cells from the bone marrow to the peripheral blood for harvesting, the current standard of care includes the administration of 5-8 daily doses of granulocyte colony stimulating factor (G-CSF), with or without 1-4 doses of plerixafor, and the performance of 1-4 apheresis sessions. For patients unable to mobilize sufficient numbers of cells for harvesting during this primary mobilization phase, rescue therapy is carried out, consisting of 1-4 additional doses of plerixafor on top of G-CSF, and the performance of an additional number of apheresis sessions as necessary. In light of this, an agent with superior mobilization activity may significantly reduce the mobilization and harvesting burden and associated risks of the ASCT process and lead to significant clinical and resource benefits.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study, has successfully completed a pre-NDA meeting with the FDA, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

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.

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 "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties 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 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; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 February 23, 2021. 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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