BioLineRx Provides Highlights from Oral Presentation Delivered at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition

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- Presentation highlighted successful GENESIS Phase 3 pivotal trial of Motixafortide plus G-CSF for stem cell mobilization in multiple myeloma patients -
- Pre-NDA meeting imminent; NDA submission anticipated in H1 2022 -

TEL AVIV, Israel, Dec. 17, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical Company focused on oncology, today provided updates from an oral presentation delivered by Dr. Zachary Crees from the Washington University School of Medicine in St. Louis (WUSTL) at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, which was held December 11-14, 2021, in Atlanta, GA, and virtually.

The oral presentation, entitled, "*Motixafortide (BL-8040) and G-CSF Versus Placebo and G-CSF to Mobilize Hematopoietic Stem Cells for Autologous Stem Cell Transplantation in Patients with Multiple Myeloma: The GENESIS Trial*" elaborated on the successful results of the Company's GENESIS Phase 3 pivotal trial which assessed Motixafortide plus G-CSF for the mobilization of stem cells in multiple myeloma patients. The study showed highly significant and clinically meaningful results supporting the use of Motixafortide on top of G-CSF for mobilization of stem cells for subsequent collection and transplantation in patients with multiple myeloma.

Recapping the efficacy data previously reported, Dr. Crees noted that 92.5% of patients in the Motixafortide+G-CSF arm achieved the primary endpoint (the mobilization of ≥6M CD34+ cells/kg in up to two apheresis sessions, p<0.0001), versus 26.2% for the placebo+G-CSF arm. Furthermore, 88.8% of patients in the Motixafortide+G-CSF arm achieved the secondary endpoint (the mobilization of ≥6M CD34+ cells/kg in one apheresis session, p<0.0001), versus 9.5% for the placebo+G-CSF arm.

Of note, Dr. Crees also indicated that 15–35% of patients still failed to yield optimal stem cell yields of ≥6M CD34+ cells/kg in two previously published plerixafor trials, even with up to four apheresis sessions. Additionally, Dr. Crees noted that advances in modern induction therapies for multiple myeloma patients have made the harvesting of a sufficient number of stem cells even more challenging, a trend that is expected to continue in the future, thus highlighting the need for new and improved mobilization therapies.

"We were very pleased that Dr. Crees had an opportunity to deliver an oral presentation at ASH, one of the most prestigious and well attended oncology gatherings of the year, to provide additional details on the outstanding results from our GENESIS Phase 3 trial," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Along with the outstanding efficacy data from the trial and the positive results from the pharmacoeconomic study that we reported on previously, trends in the treatment paradigm, whereby new induction therapies in patients make the mobilization of stem cells ever more challenging, give us great enthusiasm for this molecule and emphasize its place as part of the standard of care in autologous stem cell transplantation. We look forward to a pre-NDA meeting with FDA in the coming days."

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, 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.

Contact:
Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

Moran Meir
LifeSci Advisors, LLC
+972-54-476-4945
moran@lifesciadvisors.com

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