BioLineRx Achieves Enrollment Target in Phase 3 GENESIS Trial for Planned Interim Analysis

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- Interim analysis in GENESIS to be completed in next few months -

TEL AVIV, Israel, Aug. 19, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today announced that a sufficient number of patients (~65% of the original planned sample size) have been enrolled in the ongoing GENESIS Phase 3 trial to allow for an interim efficacy analysis to take place in the second half of 2020. This ongoing registrational study is investigating motixafortide (BL-8040) for the mobilization of hematopoietic stem cells (HSCs) for autologous transplantation in patients with multiple myeloma. If the primary endpoint is met at the time of the interim analysis, the Company plans to immediately announce the cessation of further recruitment, without the need to enroll the full planned sample size. In this case, top-line results are expected in the first half of 2021, in order to maintain study blinding for all study endpoints, including those related to engraftment, for a period of 100 days subsequent to transplantation. If the primary endpoint is not reached in the interim analysis, the Company expects recruitment will continue until the originally planned sample size is met.

"A significantly lower than anticipated patient dropout rate in the GENESIS trial triggered our decision to conduct an interim efficacy analysis, for which we have now enrolled a sufficient number of patients," said Philip Serlin, Chief Executive Officer of BioLineRx. "Once this analysis is complete, we will have enough information to decide whether to cease further enrollment or continue until completion of the original target enrollment of 177 patients. We expect the interim analysis to be completed within the next few months."

The GENESIS trial was initiated in December 2017. GENESIS is 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 HSCs for autologous transplantation in multiple myeloma patients. The primary objective of the study is to demonstrate that motixafortide on top of G-CSF is superior to G-CSF alone in the ability of mobilize ≥ $6x10^6$ CD34+ cells in up to two apheresis sessions. Secondary objectives include time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

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 currently being evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. Motixafortide is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation.

BioLineRx is 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. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

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 coronavirus outbreak; 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 March 12, 2020. 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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