



BioLineRx Announces Positive Results from Interim Analysis of GENESIS Phase 3 Trial of Motixafortide (BL-8040) in Stem Cell Mobilization

October 30, 2020

- Enrollment to cease immediately; topline data anticipated in H1 2021-

TEL AVIV, Israel, Oct. 30, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today announced positive results from a planned interim analysis of the ongoing GENESIS Phase 3 trial of motixafortide for stem cell mobilization (SCM) in multiple myeloma patients.

At a meeting of the study's independent Data Monitoring Committee (DMC), a planned interim analysis of the study's primary endpoint was conducted independently by the DMC. Based on the statistically significant evidence favoring treatment with motixafortide, the DMC issued a recommendation to the Company that patient enrollment may be ceased immediately, without the need to recruit all 177 patients originally planned for the study.

In accordance with the DMC's recommendation, study enrollment is now complete at 122 patients. Full results for the study, including secondary and exploratory efficacy endpoints, as well as extended safety data, will be announced after the last patient enrolled reaches 100 days of follow-up post-transplantation, which is expected to occur in the first half of 2021.

"The compelling results of this planned interim analysis are a very significant milestone for our Company, as our SCM program is the Company's most efficient path to registration for motixafortide," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Stem cell mobilization represents a significant unmet medical need in multiple myeloma, as between 50% and 70% of patients are poor mobilizers. We eagerly await the final results of the study, expected in the first half of next year, which we hope will support our goal of changing the treatment paradigm in autologous stem-cell mobilization, thus positioning motixafortide in combination with G-CSF as the new standard of care in this indication."

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 only one dose of motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize $\geq 6 \times 10^6$ 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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