BioLineRx Announces Successful Completion of Pre-NDA Meeting with FDA for Motixafortide for Stem Cell Mobilization in Multiple Myeloma Patients

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- NDA submission on track for H1 2022

TEL AVIV, Israel, Jan. 18, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ-CM: BLRX) (TASE: BLRX) a late clinical-stage biopharmaceutical company focused on oncology, today announced that the Company has completed a successful pre-New Drug Application (NDA) meeting with the US Food and Drug Administration (FDA) regarding Motixafortide as a novel stem-cell mobilization agent for autologous bone marrow transplantation in multiple myeloma patients.

The purpose of the meeting was to obtain agreement from the FDA on the content of the proposed NDA and, in particular, to confirm that the Company's single Phase 3 pivotal study, GENESIS, is sufficient to support an NDA submission. During the pre-NDA meeting, the FDA agreed that the proposed data package is sufficient to support an NDA submission, which the Company continues to anticipate will occur in H1 2022.

"We are highly encouraged by the collaborative pre-NDA meeting that we held with the FDA, and having confirmed alignment with the agency, our NDA submission remains on track for the first half of this year," stated Philip Serlin, Chief Executive Officer of BioLineRx. "This successful meeting continues the positive momentum generated from the compelling results of our GENESIS Phase 3 study, which demonstrate a highly significant improvement over the current standard of care, alongside the positive results of the pharmacoeconomic study that we reported more recently. As a result, Motixafortide, if approved, has the potential to become the standard-of-care mobilization therapy for all multiple myeloma patients undergoing autologous stem cell transplantation, especially in light of new and more intense induction treatment regimens given to these patients, which make stem-cell mobilization more difficult than ever before," concluded Mr. Serlin.

In May 2021, BioLineRx announced positive top-line results from its GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization for autologous bone marrow transplantation in multiple myeloma patients. The study met all primary and secondary endpoints with a very high degree of statistical significance ($p<0.0001$). Importantly, ~90% of patients went directly to transplantation after mobilizing the optimal number of stem cells following only one administration of Motixafortide and in only one apheresis session.

About BioLineRx

BioLineRx Ltd. (NASDAQ-CM: BLRX)(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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