BioLineRx Announces Submission of New Drug Application (NDA) to FDA for Motixafortide in Stem Cell Mobilization

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- *Submission based on overwhelmingly positive top-line results from GENESIS Phase 3 study*
- *Stem cell mobilization for bone marrow transplantation estimated to be > $360 million market in the U.S. (> $500 million globally), with consistent growth*

TEL AVIV, Israel, Sept. 12, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced that the Company has submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Motixafortide in stem cell mobilization (SCM) for autologous bone marrow transplantation for multiple myeloma patients.

The NDA submission is based on the overwhelmingly positive top-line results from BioLineRx's GENESIS Phase 3 trial of Motixafortide on top of G-CSF (versus placebo on top of G-CSF) 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 ($p<0.0001$). The combination was also found to be safe and well tolerated.

"The submission of our first NDA is a significant milestone for our Company and gives us potential line of sight towards launching a product that we successfully developed for an indication in substantial need of more effective treatment options," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Notably, ~90% of multiple myeloma patients in the GENESIS study went directly to transplantation after mobilizing the optimal number of stem cells following only one administration of Motixafortide and in only one apheresis session, compared to less than 10% of those receiving G-CSF alone. This high success rate has a substantial clinical benefit, especially when considering that new induction treatments are more effective than ever before but cause subsequent difficulty in mobilizing the target number of stem cells for transplantation. The high success rate may also confer significant benefits to transplant institutions through the more efficient use of apheresis units, where there is often a lack of available machines."

"The totality of data that we have compiled for Motixafortide in stem cell mobilization – both clinical and pharmacoeconomic – suggest that Motixafortide, if approved, can quickly become the key component of a new standard of care on top of G-CSF for all multiple myeloma patients undergoing autologous stem cell transplantation. The submission of our NDA brings us one critical step closer to that goal, and we look forward to working closely with the FDA during its review process," Mr. Serlin concluded.

The FDA's decision on acceptance of BioLineRx's NDA filing is expected in November. Assuming the filing is accepted, the potential PDUFA date would be in Q2 2023 (under a priority review process, if applicable) or Q3 2023 (under a standard review process). As BioLineRx finalizes its commercialization plans for Motixafortide in the U.S., the Company continues to advance critical pre-launch activities, required under any commercialization scenario, to ensure a robust and targeted commercial launch very soon after its PDUFA date, assuming FDA approval.

About BioLineRx

BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. 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 in the US, has successfully completed a pre-NDA meeting with the FDA, and has completed an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy. A randomized phase 2b study with 200 patients in combination with PD1 and chemotherapy as a first-line PDAC therapy will initiate in 2023.

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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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 and ability to access sufficient 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; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the

factors discussed above. 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 16, 2022. 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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