BioLineRx Announces U.S. Commercialization Plan for APHEXDA (Motixafortide) in Stem Cell Mobilization

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- Company to accelerate availability to patients and maximize value through independent commercialization to well-defined U.S. transplant center community
- Veteran product launch leader Holly May named President, BioLineRx USA
- Company introduces APHEXDA as Motixafortide's FDA approved trade name
- Company to host Investor and Key Opinion Leader webinar TOMORROW, Wednesday, September 28, at 9:00 a.m. EDT

TEL AVIV, Israel, Sept. 27, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced its U.S. commercialization plan for APHEXDA (Motixafortide) in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients. If approved, the Company intends to commercialize APHEXDA in the U.S. independently in order to accelerate its availability to patients and to maximize the value of this innovative therapeutic candidate. To lead its U.S. operations and drive commercial strategy, the Company has appointed commercial product veteran Holly May to the role of President, BioLineRx USA.

In the U.S., autologous stem cell transplants for patients with multiple myeloma and other conditions are highly concentrated within academic and regional centers. To support a robust commercial launch, the Company will employ a small and targeted sales force to support outreach to this well-defined community.

"We are excited to announce our plan to commercialize Motixafortide, now known by its FDA approved trade name APHEXDA, independently in the U.S., assuming FDA approval next year," said Philip Serlin, Chief Executive Officer of BioLineRx. "Our approach ensures focused outreach to transplant centers and enhanced value for the Company over other potential commercialization approaches examined. Since the beginning of 2022, we have been advancing key pre-launch activities. Our progress, together with our recent financings, puts us in an ideal position to efficiently build the additional infrastructure and targeted sales team to ensure the rapid uptake of APHEXDA."

"Our independent market research suggests that the U.S. market for mobilization agents used in stem cell transplants is approximately $360 million annually and growing," said Holly May, President, BioLineRx USA. "Given the totality of clinical and pharmacoeconomic data that we have compiled to date, we believe APHEXDA, if approved, can quickly become part of a new standard of care, allowing us to capture a significant share of this opportunity. Our U.S. commercial team is actively engaged in launch preparedness and excited about the potential of bringing this important therapeutic candidate to patients."

The Company recently announced that it submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Motixafortide in stem cell mobilization 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.

Investor and Key Opinion Leader Webinar
BioLineRx will provide more detail around its U.S. launch plans during an Investor and Key Opinion Leader Webinar that is occurring tomorrow, Wednesday, September 28, at 9:00 a.m. EDT.

The webinar will feature a presentation by Dr. John F. DiPersio, Chief of the Division of Oncology, Washington University School of Medicine, St. Louis, and lead investigator of BioLineRx's GENESIS Phase 3 clinical study (the basis for the Company's recently submitted New Drug Application), who will highlight the unmet need and current treatment landscape for the mobilization of stem cells (SCM) for multiple myeloma patients undergoing autologous stem cell transplantation.

Following Dr. DiPersio's presentation, Lissa Gray, RN, who heads BioLineRx's patient advocacy program, will moderate a panel discussion between an apheresis nurse, a multiple myeloma patient who underwent apheresis, and her caretaker, to provide a detailed assessment of the current treatment experience.

Holly May, President of BioLineRx USA, will then provide insight into the SCM market opportunity, as well as expand upon the Company's plans to commercialize APHEXDA independently in the U.S., if approved.

Interested parties may register for the webinar here.

A replay of the webinar will be available on the Company's Investor Relations page approximately two hours after the event's completion. The webinar replay will be available until October 31, 2022.

About the GENESIS Trial
The GENESIS trial (NCT03246529) was initiated in December 2017. GENESIS was 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 hematopoietic stem-cells for autologous transplantation in multiple myeloma patients. The primary objective of the study was to demonstrate that only one dose of Motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize ≥ 6 million CD34+ cells in up to two apheresis sessions. A key secondary objective of the study was to demonstrate that only one dose of Motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize ≥ 6 million

CD34+ cells in only one apheresis session. In this regard, ~90% of patients in the GENESIS study went directly to transplantation after mobilizing the optimal number of stem cells following only one administration of Motixafortide on top of G-CSF and in only one apheresis session, compared to less than 10% of those receiving G-CSF alone. Additional objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

About Multiple Myeloma
Multiple myeloma is an incurable blood cancer that affects some white blood cells called plasma cells, which are found in the bone marrow. When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.

About Autologous Stem Cell Transplantation
Autologous stem cell transplantation (ASCT) is part of the standard treatment paradigm for a number of blood cancers, including multiple myeloma. In the U.S., nearly 15,000 ASCTs are performed each year with the majority in patients with multiple myeloma. The current standard of care includes the administration of 5-8 daily doses of granulocyte colony stimulating factor (G-CSF), with or without 1-4 doses of plerixafor, and the performance of 1-4 apheresis sessions. For patients unable to mobilize sufficient numbers of cells for harvesting during this primary mobilization phase, rescue therapy is carried out, consisting of 1-4 additional doses of plerixafor on top of G-CSF, and the performance of an additional number of apheresis sessions as necessary. In light of this, an agent with superior mobilization activity may significantly reduce the mobilization and harvesting burden and associated risks of the ASCT process and lead to significant clinical and resource benefits.

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.

Forward Looking Statement
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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