BioLineRx Announces Positive Top-Line Results from GENESIS Phase 3 Trial of Motixafortide in Stem-Cell Mobilization for Autologous Bone Marrow Transplantation in Multiple Myeloma Patients

May 4, 2021 11:00 AM IDT

- Study met all primary and secondary endpoints with exceptionally high level of statistical significance (p<0.0001) -

- Motixafortide + G-CSF demonstrated a 4.9-fold increase versus G-CSF alone in achieving primary endpoint of target mobilization in up to TWO apheresis sessions -

- 88.3% of patients receiving Motixafortide + G-CSF underwent transplantation after only ONE apheresis session, compared to 10.8% for G-CSF alone; supports Motixafortide on top of G-CSF as new standard of care in this indication -

- Management to hold conference call today, May 4, at 10:00 am EDT -

TEL AVIV, Israel, May 4, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today announced positive top-line results from the Company's GENESIS Phase 3 trial evaluating its lead clinical candidate, Motixafortide, in combination with granulocyte colony stimulating factor (G-CSF, the standard of care in this indication), for hematopoietic stem-cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

An analysis of data on all 122 enrolled patients (the intent to treat, or ITT, population) found highly statistically significant evidence across all primary and secondary endpoints favoring Motixafortide in addition to G-CSF, as compared to placebo plus G-CSF. In addition, the combination was found to be safe and well tolerated.

The primary endpoint of the study demonstrated a 4.9-fold increase (70.0% vs 14.3%; difference 54.6%; 95% CI 39.7-69.5%; p<0.0001) in the proportion of patients in the treatment arm, as compared to the control arm mobilizing ≥ 6 million CD34+ cells/kg in up to two apheresis sessions, and after only one administration of Motixafortide. This translates to an odds-ratio of 12.9.

The study also achieved its main secondary endpoint, demonstrating a 14.1-fold increase (67.5% vs 4.8%; difference 61.7%; 95% CI 49.5-73.8%; p<0.0001) in the proportion of patients in the treatment arm, as compared to the control arm, who mobilized ≥ 6 million CD34+ cells/kg in just one apheresis session. This translates to an odds-ratio of 56.0.

Other important data from the study include median number of CD34+ cells collected on the first day of apheresis (8.5 million in the treatment arm vs 1.5 million in the control arm) – a 5.6-fold increase. The addition of Motixafortide to G-CSF also allowed 88.3% of patients to undergo transplantation after only one apheresis session, compared to 10.8% in the G-CSF arm – an 8.2-fold increase. Engraftment endpoints, including the number of days needed for engraftment, success of engraftment and the durability of engraftment 100 days post-transplant, further support the study's success.

"The results of the GENESIS study are extremely impressive, and all the more so when considering that almost 90% of the patients in the treatment arm proceeded to transplantation after only one apheresis session," stated John DiPersio, MD, Washington University School of Medicine, and lead investigator of the study. "This is a great achievement in alleviating the burden for the patients and reducing hospital resources. I believe these results make the combination of Motixafortide and G-CSF a very attractive candidate for use in all patients with multiple myeloma undergoing autologous stem-cell transplantation."

"These strikingly positive data significantly exceeded our expectations, and are truly transformational for our company," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The statistical significance across all primary and secondary endpoints was consistent across twelve different sensitivity analyses. These results support our goal of becoming the standard of care for autologous bone-marrow transplantation, providing a strong clinical and pharmaco-economic advantage for its use, on top of G-CSF, in all transplant procedures.

"We are working aggressively to gain regulatory approval for Motixafortide in this transplant setting for multiple myeloma patients – with plans to make an NDA submission in the first half of next year – and we are also pressing forward to unlock the full potential of this therapy in this and other stem-cell mobilization indications. I would like to express our sincere thanks to the patients and investigators who participated in the study and enabled its great success," Mr. Serlin concluded.

Conference Call and Webcast Information
BioLineRx will hold a conference call today, Tuesday, May 4, 2021 at 10:00 a.m. EDT. To access the conference call, please dial +1-866-860-9642 from the US or +972-3-918-0644 internationally. The call will also be available via webcast and can be accessed through the Investor Relations page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available for a limited time approximately two hours after completion of the live conference call on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until May 6, 2021; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

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. Additional objectives

included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters. Local laboratories and a central laboratory were used to determine CD34+ cell yields. For regulatory purposes, efficacy endpoints were calculated using the percentage of CD34+ cells determined by the central laboratory. The local laboratory values were used for all clinical decisions, including the number of apheresis days and the decision to proceed to transplantation.

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 that was successfully evaluated in a Phase 3 study in stem-cell mobilization for autologous bone-marrow transplantation. 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 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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