BioLineRx Announces Initiation of Phase 1b Clinical Trial in Patients with Acute Respiratory Distress Syndrome (ARDS) Secondary to COVID-19 and Other Respiratory Viral Infections

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- Investigator-initiated study, led by Wolfson Medical Center, to evaluate Motixafortide in up to 25 patients hospitalized with ARDS -

- Results of preliminary analysis expected in H1 2021-

TEL AVIV, Israel, Nov. 18, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical Company focused on oncology, today announced that the Company's lead drug candidate, the CXCR4-inhibitor Motixafortide, will be evaluated in an investigator-initiated clinical trial in patients suffering from acute respiratory distress syndrome (ARDS) secondary to COVID-19 and other respiratory viral infections.

The open-label, single-arm, Phase 1b study will be conducted at the Wolfson Medical Center in Holon, Israel, with Dr. Yasmin Maor, Head of the Infectious Disease Unit, as lead investigator.

"Severe COVID-19 cases, where patients are hospitalized with ARDS and require ventilation, have generated renewed interest in the underlying pathology of acute respiratory stress disorder," noted Dr. Maor. "Substantial data is emerging regarding the involvement of neutrophils, neutrophil extracellular traps (NETs), monocytes and macrophages in the development of ARDS secondary to COVID-19 and other viral infections; as well as the key involvement of CXCR4 as a mediator of those cells in the inflamed pulmonary tissue. Based on the scientific data indicating the importance of blocking the CXCR4/CXCL12 axis during ARDS, Motixafortide could be of potential benefit for such patients. COVID-19 case counts are again surging in many parts of the world and addressing ARDS has become a top global health priority."

The primary endpoint of the study is to assess the safety of Motixafortide in patients with ARDS secondary to COVID-19 and other respiratory viral infections. Respiratory parameters and inflammatory biomarkers will be assessed as exploratory endpoints. Up to 25 patients will be enrolled, with a preliminary analysis planned after ten patients have completed the initial treatment period. Based on the preliminary evaluation, a decision to continue or not will be conducted by Dr. Maor, together with the Company.

"We believe there is strong scientific rationale for exploring Motixafortide in ARDS, and we are grateful to Dr. Maor for initiating this study," stated Philip Serlin, Chief Executive Officer of BioLineRx. "We have compiled a significant body of data demonstrating Motixafortide's utility as a best-in-class CXCR4 inhibitor and we are eager to evaluate its effectiveness in blunting the cytokine storm that is associated with poor COVID-19 infection outcomes. We look forward to results from the preliminary analysis in the first half of next year.

"In parallel, we remain on track to announce full data from our Phase 2a COMBAT/KEYNOTE-202 study in pancreatic cancer, as well as interim results from our Phase 2b BLAST study in AML, by the end of this year," Mr. Serlin concluded.

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 3 study in stem cell mobilization for autologous bone-marrow transplantation, and for which positive data in respect of the study's primary endpoint was recently announced from an interim analysis, resulting in early cessation of recruitment. Motixafortide is also 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, as well as a Phase 2b study in consolidation AML.

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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