BioLineRx Announces Notice of Allowance from USPTO for Patent Covering Motixafortide (BL-8040) in Combination With Anti-PD-1 for the Treatment of Any Type of Cancer

February 27, 2020

TEL AVIV, Israel, Feb. 27, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX), (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, announced today that a Notice of Allowance has been issued by the United States Patent and Trademark Office (USPTO) for a patent application claiming the use of motixafortide (BL-8040), a novel immunotherapy compound, combined with any PD-1 inhibitor, for the treatment of any type of cancer.

The PD-1 antagonist can be any agent that prevents and/or inhibits the biological function and/or expression of PD-1, such as pembrolizumab (KEYTRUDA®). The targeted cancer can be solid, non-solid, and/or a cancer metastasis.

This patent, whenmedi issued, will be valid until July 2036 with a possibility of up to five years patent term extension. Additional corresponding patent applications are pending in Europe, Japan, China, Canada, Australia, India, Korea, Mexico, Brazil and Israel.

"We are extremely pleased to receive this valuable notice of allowance from the USPTO, which entitles us to long-term, highly enforceable and broad patent protection for our lead product, motixafortide, in combination with any PD-1 inhibitor, and more importantly, for all cancer indications, including, of course, any solid tumor," stated Philip Serlin, Chief Executive Officer of BioLineRx. "This important patent allowance also supports our ongoing Phase 2a COMBAT/KEYNOTE-202, for which we have recently completed patient recruitment in the triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA and chemotherapy. Following promising initial results demonstrating robust and durable responses to the triple combination treatment, we look forward to the progression-free and overall survival data from the triple combination arm expected in mid-2020."

The COMBAT/KEYNOTE-202 Study

The Phase 2a COMBAT/KEYNOTE-202 study was originally designed as an open-label, multicenter, single-arm trial to evaluate the safety and efficacy of the dual combination of motixafortide and KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in over 30 subjects with metastatic pancreatic adenocarcinoma. The study was primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies, and was carried out in the US, Israel and additional territories. The study is being conducted by BioLineRx under a collaboration agreement signed in 2016 between BioLineRx and MSD, through a subsidiary.

In July 2018, the Company announced the expansion of its immuno-oncology collaboration with MSD to include the triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA and chemotherapy as part of the Phase 2a COMBAT/KEYNOTE-202 study. In January 2020, the Company announced completion of recruitment of the 40 patients planned for the triple combination arm of the study.

About Motixafortide in Cancer Immunotherapy

Motixafortide is targeting CXCR4, a chemokine receptor and a well validated therapeutic target that is over-expressed in many human cancers including PDAC. CXCR4 plays a key role in tumor growth, invasion, angiogenesis, metastasis and therapeutic resistance, and CXCR4 overexpression has been shown to be correlated with poor prognosis.

Motixafortide is a short synthetic peptide used as a platform for cancer immunotherapy with unique features allowing it to function as a best-in-class antagonist of CXCR4. It shows high-affinity, long receptor occupancy and acts as an inverse agonist.

In a number of clinical and preclinical studies, motixafortide has been shown to affect multiple modes of action in "cold" tumors, including immune cell trafficking, tumor infiltration by immune effector T cells, and reduction in immunosuppressive cells (such as MDSCs) within the tumor niche, turning "cold" tumors, such as pancreatic cancer, "hot" (i.e., sensitizing them to immune checkpoint inhibitors and chemotherapy).

About BioLineRx

BioLineRx Ltd. (NASDAQ: BLRX), (TASE: BLRX) is a 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, is a cancer therapy platform currently 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. Motixafortide is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation.

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. Some of these risks are: changes in relationships with collaborators; the impact of competitive products

and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. 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 28, 2019. 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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