BioLineRx Receives Orphan Drug Designation for Motixafortide (BL-8040) for the Treatment of Pancreatic Cancer in Europe

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TEL AVIV, Israel, Jan. 14, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today announced that the European Commission (EC) has granted Orphan Drug Designation to its lead oncology candidate, Motixafortide (BL-8040), for the treatment of pancreatic cancer, based on a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). Last year, Motixafortide received Orphan Drug Designation for the treatment of Pancreatic Cancer from the US Food and Drug Administration (FDA).

"The Orphan Drug status we received for Motixafortide, from both the US and European regulatory bodies, is of significant strategic importance for the development of our lead product for the treatment of pancreatic cancer, an extremely difficult to treat indication with a poor response to the currently available treatments," stated Philip Serlin, Chief Executive Officer of BioLineRx. "We recently reported very encouraging initial data from the triple combination arm of our ongoing Phase 2a COMBAT/KEYNOTE-202 study in second line metastatic pancreatic cancer patients, which served as the basis for this ODD, and we believe that this designation will maximize the potential to make this new treatment available for patients in the fastest way possible."

Motixafortide is 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 Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada).

The EMA grants orphan medicinal product designation to investigational drugs intended to treat, prevent or diagnose a life-threatening or chronically debilitating disease affecting fewer than five in 10,000 people in the EU and for which no satisfactory treatment is available or, if such treatment exists, the medicine must be of significant benefit to those affected by the condition. Orphan medicinal product designation provides regulatory and financial incentives for companies to develop and market therapies, including ten years of market exclusivity, protocol assistance, fee reductions and EU-funded research.

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, into "hot" (i.e., sensitizing them to immune checkpoint inhibitors and chemotherapy).

About Pancreatic Cancer

Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. Its incidence rate in the US is estimated at 3.2% of new cancer cases. Each year, about 185,000 individuals globally are diagnosed with this condition, and an estimated 55,000 individuals were diagnosed with pancreatic cancer in the US during 2018. Symptoms are usually non-specific and as a result, pancreatic cancer is often not diagnosed until it reaches an advanced stage. Surgical resection does not offer adequate treatment since only 20% of patients have resectable tumors at the time of diagnosis. The overall five-year survival rate among all pancreatic cancer patients is 7-8%, which constitutes the highest mortality rate among solid tumor malignancies. The overall median survival is less than one year from diagnosis, highlighting the need for the development of new therapeutic options.

Despite advances in chemotherapeutics and immunotherapy, increases in median and overall survival rates in pancreatic cancer have been modest. Pancreatic cancer remains an area of unmet medical need, with no new approved therapies since the approval of nab-paclitaxel in combination with gemcitabine (Abraxane®) for first-line treatment in 2013 and Onivyde® in combination with fluorouracil and leucovorin for second-line treatment in 2015. The limited clinical benefits demonstrated by these existing standard treatment options reinforce the need for additional approaches.

About BioLineRx

BioLineRx Ltd. (NASDAQ/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 (BL-8040), 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. In addition, the Company has an ongoing collaboration agreement with Genentech, a member of the Roche Group, evaluating Motixafortide in combination with Genentech's atezolizumab in two Phase 1b/2 solid tumor studies.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being undergoing 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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