# BioLineRx Receives Orphan Drug Designation From the FDA for its Lead Therapeutic Candidate BL-8040 for the Treatment of Pancreatic Cancer

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BioLineRx Ltd. (NASDAQ: BLRX) (TASE:BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to its lead oncology candidate, BL-8040, for the treatment of pancreatic cancer.

"Orphan Drug Designation in pancreatic cancer is a very important milestone in the development plan of BL-8040, and joins previously approved orphan designations by the FDA for BL-8040 in AML and stem-cell mobilization," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Despite advances in the treatment of various cancers with immune checkpoint inhibitors, pancreatic cancer is refractory to these treatment options, and remains an area of significant unmet medical need. We have previously reported encouraging clinical data supporting the potential of BL-8040 as part of an immunotherapy combination treatment in pancreatic cancer, and we look forward to top-line results from our ongoing pancreatic clinical studies later this year."

BL-8040 is currently being investigated in clinical studies for the treatment of pancreatic cancer under two separate immuno-oncology collaborations – one with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), and a second collaboration with Genentech, a member of the Roche Group.

Orphan Drug Designation by the FDA entitles BioLineRx to seven years of market exclusivity for the use of BL-8040 for the treatment of pancreatic cancer, if approved, plus significant development incentives, including tax credits related to clinical trial expenses, an exemption from the FDA-user fee, and FDA assistance in clinical trial design.

**About BL-8040**

BL-8040 is a short synthetic peptide for the treatment of hematological malignancies, solid tumors, and stem cell mobilization. It functions as a high-affinity best-in-class antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in many human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells and immune-cells, sensitization of cancer cells to chemo- and bio-based anti-cancer therapies, and direct anti-cancer effect by inducing programmed cell death (apoptosis). BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

**About Pancreatic Cancer**

Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. Its incidence rate in the U.S. 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 U.S. 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. Even among patients who undergo resection for pancreatic cancer and have tumor-free margins, the five-year survival rate is only 10%-25%. The overall five-year survival rate among 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 is a clinical-stage biopharmaceutical company focused on oncology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

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 6, 2018. 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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