BioLineRx Announces Preliminary Phase 2a Data from Triple Combination Arm of COMBAT/KEYNOTE-202 Study in Second Line Patients With Metastatic Pancreatic Cancer

December 5, 2019

- Combination of BL-8040, KEYTRUDA® and chemotherapy showed high level of disease control, including 4 partial responders and 8 patients with stable disease out of 15 evaluable patients -

- Study is ongoing; progression free survival and overall survival not yet reached; survival data expected in mid-2020 -

- Updated data will be disclosed at an oral presentation at ESMO IO on December 13th -

- The results will be discussed at an investor breakfast and live webcast hosted by BioLineRx today in New York, from 8:10-9:30 am EST -

TEL AVIV**,** Israel, Dec. 5, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today preliminary data from the triple combination arm of the ongoing Phase 2a COMBAT/KEYNOTE-202 study showing that the combination of BL-8040 (a CXCR4 inhibitor), KEYTRUDA® and chemotherapy shows high response and disease control rates in patients with metastatic pancreatic cancer. The data, summarized in an abstract published today, entitled, "A Multi-Center Phase 2a Trial to Assess the Safety and Efficacy of BL-8040 (a CXCR4 inhibitor) in Combination with Pembrolizumab and Chemotherapy in Patients with Metastatic Pancreatic Adenocarcinoma (PDAC)," will be presented and discussed as a proffered paper (oral) presentation on Friday, December 13 at the European Society of Medical Oncology Immuno-Oncology Congress (ESMO IO) 2019, which is being held December 11-14 at the Palexpo in Geneva, Switzerland.

Manuel Hidalgo, MD, PhD, Chief of the Division of Hematology and Medical Oncology, Senior Member of the Meyer Cancer Center at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center, and principal investigator of this study, said, "Metastatic pancreatic cancer has the worst prognosis of all solid tumors, with five-year survival rates of 3%, and a very poor response to the currently available immunotherapy treatments that are transforming care in other cancer indications. Therefore, it is highly important to develop novel combination treatments that will increase the responsiveness and survival of pancreatic cancer patients to immunotherapy. We are encouraged by these preliminary results and look forward to sharing additional data from this important trial next week at ESMO IO."

Preliminary Data from Triple Combo Arm of the COMBAT/KEYNOTE-202 Study

As of September 30, 2019 (the data cutoff date for the abstract), 22 patients were dosed (out of ~40 planned), of which 15 were evaluable. All patients enrolled were originally diagnosed with stage IV metastatic pancreatic adenocarcinoma (PDAC) and had progressed following first-line treatment with gemcitabine-based chemotherapy.

- Best response for the evaluable population of 15 patients showed 4 partial response (PR) and 8 stable disease (SD) patients – resulting in overall disease control in 12 out of 15 patients;
- Study is ongoing and median progression free survival (PFS) and overall survival (OS) were not yet reached; survival data remain on track for mid-2020;
- The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone. Fifteen serious adverse events (SAEs) were reported by 10 patients and 2 patients discontinued the study due to SAEs.

"We are very excited by the preliminary data from this triple combination arm of our Phase 2a pancreatic study under our collaboration with Merck," stated Philip Serlin, Chief Executive Officer of BioLineRx. "These data appear to confirm our hypothesis relating to the synergistic effect of cytotoxic chemotherapy, together with the T-cell trafficking, tumor microenvironment modulation and T-cell infiltration effects of BL-8040 seen in PDAC patients from multiple Phase 2 trials in combination with checkpoint inhibitors. Despite metastatic PDAC being one of the toughest diseases to treat, with so many prior clinical failures, we believe this combination of BL-8040, KEYTRUDA and chemotherapy may provide real hope to pancreatic cancer patients. We look forward to the additional data to be shared next week, as well as the complete study results expected to be released in mid-2020."

Investor Breakfast Meeting Today in New York

The preliminary results will be discussed at an Investor/Analyst Breakfast Meeting being hosted by BioLineRx today, December 5, 2019, in New York, between 8:10 am and 9:30 am EST. A live webcast and replay of the event will be accessible here.

Design of Triple Combination Arm of COMBAT/KEYNOTE-202 Study

The triple combination arm focuses on second-line pancreatic cancer patients and is expected to include approximately 40 patients originally diagnosed with unresectable metastatic pancreatic adenocarcinoma who have progressed following first-line gemcitabine-based therapy. Patients receive BL-8040 monotherapy priming treatment for five days, followed by combination cycles of chemotherapy (Onivyde®/5-fluorouracil/leucovorin), KEYTRUDA® and BL-8040 until progression. The primary endpoint of the study is the objective response rate (ORR). Secondary endpoints include overall survival, progression free survival, and disease control rate.

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 combination of BL-8040 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 BL-8040, KEYTRUDA and chemotherapy as part of the Phase 2a COMBAT/KEYNOTE-202 study.

About BL-8040 in Cancer Immunotherapy

BL-8040 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.

BL-8040 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, BL-8040 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 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, 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. BL-8040 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 BL-8040 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.

Dr. Hidalgo is a paid consultant for PharmaCyte Biotech Inc., InxMed, Agenus, Takeda and Tolero Pharmaceuticals, which are clinical-stage companies focused on treatments for cancer and other diseases. Dr. Hidalgo also has stock in Agenus and PharmaCyte Biotech Inc., as well as Champions Oncology Inc., a company that supports oncology drug development. Additionally, he has received travel reimbursement from PanCan, Takeda, AACR, Agenus and BioLineRx.

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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