BioLineRx Announces Publication of Data from Ongoing COMBAT/KEYNOTE-202 Clinical Trial in Nature Medicine

May 27, 2020 11:00 AM IDT

TEL AVIV, Israel, May 27, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical Company focused on oncology, today announced that a paper, entitled 'BL-8040, a CXCR4 Antagonist, in Combination with Pembrolizumab and Chemotherapy for Pancreatic Cancer: The COMBAT Trial,' has been published in the peer-reviewed journal *Nature Medicine*.

The paper highlights previously disclosed biomarker and clinical data from the Company's ongoing COMBAT/KEYNOTE-202 clinical trial, consisting of two cohorts assessing the safety, efficacy and immunobiological effects in patients with metastatic pancreatic ductal adenocarcinoma (metastatic pancreatic cancer, or PDAC).

The first cohort evaluated the combination of motixafortide (BL-8040) and pembrolizumab in 37 patients refractory to 1-4 prior lines of chemotherapy. The primary outcome measure was objective response rate (ORR). Secondary outcomes were overall survival (OS), disease control rate (DCR) and safety. The DCR was 34.5% in the evaluable population (N=29), including nine patients (31%) with stable disease and one patient (3.4%) with partial response. Median OS (mOS) was 3.3 months. Notably, in the subset of second-line patients (N=16), mOS was 7.5 months. In addition, motixafortide monotherapy, as well as the dual combination, showed increased CD8+ effector T-cell tumor infiltration, decreased myeloid derived suppressor cells in the tumor microenvironment, and a decrease in circulating immuno-suppressive Tregs, thereby confirming the mechanism of action originally hypothesized and previously seen only in animal models.

Based on the clinical and immuno-biological effects observed in the first cohort, as well as preclinical data showing that the combination of chemotherapy with motixafortide and a PD-1 inhibitor results in increased anti-tumor effects, a second study cohort was initiated, incorporating the triple combination of motixafortide, pembrolizumab and chemotherapy. This cohort will include approximately 40 subjects with metastatic PDAC at first diagnosis, and with disease progression following first-line gemcitabine-based treatment. Preliminary data from 22 patients in the second cohort were available at the date of paper submission. This data showed ORR, DCR and median duration of clinical benefit of 32%, 77% and 7.8 months, respectively.

"PDAC is among the most difficult cancers to treat, due to its generally late stage at the time of initial diagnosis, its relative chemoresistance and its highly immunosuppressive microenvironment. In light of this, PDAC has shown a poor response to immunotherapies such as checkpoint inhibitors that have positively impacted patient prognoses in many other cancer types," stated Philip Serlin, Chief Executive Officer of BioLineRx.

"This paper describes that the dual combination of motixafortide and KEYTRUDA® showed encouraging clinical activity, as well as proof-of-mechanism, in one of the coldest tumors. It also presents preliminary data from the triple combination suggesting that CXCR4/PD-1 blockade may enhance the benefit of chemotherapy in patients suffering from PDAC. We look forward to progression free survival and overall survival data later this year. We believe that our findings to date warrant further evaluation of this promising combination via a randomized trial," Mr. Serlin concluded.

The Company completed enrollment in the triple combination arm in January 2020 and anticipates reporting progression-free survival and overall survival data mid-year.

The paper is available online at: https://www.nature.com/articles/s41591-020-0880-x.

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. 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 Ltd. (NASDAQ: BLRX) (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 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 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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