



BioLineRx Announces Updated Phase 2a Data From Triple Combination Arm of COMBAT/KEYNOTE-202 Study in Patients With Second-line Metastatic Pancreatic Cancer

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- **Combination of BL-8040, KEYTRUDA® and chemotherapy demonstrates a 32% overall response rate and a 77% disease control rate out of 22 currently evaluable patients -**
- **Median duration of clinical benefit for all 17 patients with disease control (7 PR and 10 SD patients) is 7.8 months -**
- **Patient recruitment nears completion, with 36 out of 40 patients enrolled -**
- **Progression free survival and overall survival data remain on track for mid-2020 -**
- **Management will discuss results on conference call today, December 13, at 8:30 am EST -**

TEL AVIV, Israel, Dec. 13, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today updated data from the triple combination arm of the ongoing Phase 2a COMBAT/KEYNOTE-202 study. The data was delivered today in an oral presentation 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)", at the [European Society of Medical Oncology Immuno-Oncology Congress \(ESMO IO\) 2019](#), which is being held December 11-14 in Geneva, Switzerland. The full presentation is available on [the Company's website](#).

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

As of today's date, 36 out of 40 patients have been enrolled in the study. As of December 5, 2019 (the cutoff date for the presentation data), 30 patients were evaluable for safety and 22 were evaluable for efficacy. 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 22 patients showed 7 partial response (PR) and 10 stable disease (SD) patients – resulting in an overall response rate (ORR) of 32% and a disease control rate (DCR) of 77%; this compares favorably to the current chemotherapy standard-of-care treatment in second-line patients with ORR of 17% and DCR of 52%;
- The combination showed continuity of effect – 5 patients with stable disease became partial responders as treatment continued;
- Out of the 7 partial responders, 5 are still on treatment, with a current maximum treatment time of 330+ days; and 4 responders showed a reduction in tumor burden of >50%;
- Median duration of clinical benefit until progression for the 17 patients with disease control (7 PR and 10 SD patients) is 7.8 months;
- The study is ongoing; progression-free and overall 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; adverse event (AE) and severe adverse event (SAE) profiles are as expected with chemotherapy-based treatment regimens.

"Metastatic pancreatic cancer has a very poor response to chemotherapy, and immunotherapy treatments have failed to show any effect as single agents," said Manuel Hidalgo, MD, PhD, Chief of the Division of Hematology and Medical Oncology and a Senior Member of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center, and principal investigator of this study. "These promising initial results presented today show an overall response rate almost double the current chemotherapy standard-of-care treatment in second-line patients. The results are even stronger when taking into account the extended durability of clinical benefit seen to date in this study (median of 7.8 months), compared to approximately three months of response duration with other treatments for second-line pancreatic cancer. I look forward to the survival data expected in mid-2020."

"We are very excited by the positive data accumulating 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 continue to confirm our hypothesis relating to the synergistic effect of cytotoxic chemotherapy, along with the trafficking, tumor microenvironment modulation and T-cell infiltration effects seen in PDAC patients from previous dual combination trials of BL-8040 with checkpoint inhibitors. It is therefore very encouraging to see robust and durable responses to the triple combination treatment, especially as we continue to see a trend of patients receiving treatment for an extended period that move from stable disease to partial response. We hope to see these results translate into an extended survival benefit for these patients, which we expect to announce in mid-2020, and we hope will pave the way for use of immunotherapy in pancreatic cancer and in other cold tumors."

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).

Conference Call and Webcast Information

BioLineRx will hold a conference call today, December 13, 2019 at 8:30 a.m. EST. To access the conference call, please dial +1-888-668-9141 from the U.S. or +972-3-918-0609 internationally. The call will also be available via webcast and can be accessed through the [Investor Relations](#) page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call on the [Investor Relations](#) page of BioLineRx's website. A dial-in replay of the call will be available until December 15, 2019; please dial +1-888-782-4291 from the U.S. or +972-3-925-5927 internationally.

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, 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.biogenerx.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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