SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of November 2019

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BioLineRx Ltd.

(Translation of registrant's name into English)

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2 HaMa'ayan Street
Modi'in 7177871, Israel
(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☑ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes ☐ No ☑

On November 5, 2019, the registrant issued the press release which is filed as Exhibit 1 to this Report on Form 6-K.

This Form 6-K, including all exhibits hereto, is hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioLineRx Ltd.

By: /s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Dated: November 5, 2019

Exhibit 1

For Immediate Release

BioLineRx Announces BL-8040 in Combination with KEYTRUDA Shows Clinical Activity in Heavily Pretreated Metastatic Pancreatic Cancer Patients

- Results of the Phase 2b trial are being presented by MD Anderson Cancer Center at SITC 2019 -

Tel Aviv**,** Israel – November 5, 2019 - BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today results of a Phase 2b trial assessing the efficacy of BL-8040 in combination with KEYTRUDA® (pembrolizumab) for the treatment of metastatic pancreatic cancer. The data demonstrated that the dual combination shows clinical activity in heavily pretreated patients. The results of this investigator-sponsored study will be presented by MD Anderson Cancer Center in a poster titled, "A phase IIB study of Pembrolizumab plus BL-8040 in metastatic pancreatic cancer: Clinical outcomes and biological correlates," at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting, which is being held November 6-10, 2019 in National Harbor, Maryland.

"These promising data demonstrate that the dual combination of BL-8040 and KEYTRUDA shows encouraging clinical activity even in an extremely challenging patient population of heavily pretreated pancreatic cancer patients. The results confirm similar findings, as measured by disease control and extended overall survival, from the dual combination arm of the Phase 2a COMBAT/KEYNOTE-202 study previously announced, thus reaffirming the strong rationale for continued development," said Philip Serlin, Chief Executive Officer of BioLineRx. "We are now eagerly looking forward to announcing results from the ongoing triple combination arm of the COMBAT/KEYNOTE-202 study, investigating the effect of BL-8040, KEYTRUDA and chemotherapy on metastatic pancreatic cancer patients, by the end of the year. We are rapidly approaching this important data milestone, and believe that BL-8040 as part of a combination regimen could represent a significant advancement in the treatment of pancreatic cancer."

This open-label Phase 2b study, under a clinical collaboration between BioLineRx and MD Anderson Cancer Center, enrolled 20 metastatic pancreatic cancer patients who progressed after at least one prior line of chemotherapy. Patients were treated for two weeks with BL-8040 as a single agent (1.25 mg/kg) followed by 3-week cycles of BL-8040 (days 1, 4, 8 and 11) in combination with pembrolizumab (day 1). Biopsies for tumor biology were performed before treatment, after BL-8040 monotherapy (optional), and after the drug combination.

Of the 20 patients enrolled, 15 were evaluable for the primary endpoint of radiologic response. Of these 15 evaluable patients, one patient showed a partial response, two patients had stable disease and 12 patients experienced disease progression, resulting in a disease control rate of 20%. The overall median time to progression was two months, while the median time to progression for patients showing disease control was seven months. Median overall survival was seven months, while median survival for the patients showing disease control was 12 months. The combination was generally well tolerated with injection site discomfort being the most commonly reported adverse event. Four patients experienced grade 3 toxicities and one patient had a grade 4 dyspnea.

In addition to the improved survival, tumor biopsies showed greater infiltration of T cells, especially cytotoxic CD8+ T cells, into the tumor niche in patients who demonstrated clinical benefit, compared with patients that experienced disease progression.

About BL-8040
BL-8040 is a short synthetic peptide that functions as a high-affinity best-in-class antagonist for CXCR4, a chemokine receptor over-expressed in many human cancers. CXCR4 has been shown to be correlated with poor prognosis, and plays a key role in tumor growth, invasion, angiogenesis, metastasis and therapeutic resistance. CXCR4 is also directly involved in the homing and retention of hematopoietic stem cells (HSCs) and various hematological malignant cells in the bone marrow.

In a number of clinical and preclinical studies, BL-8040 has shown a critical role in immune cell trafficking, tumor infiltration by immune effector T cells and reduction in immunosuppressive cells within the tumor niche, turning “cold” tumors, such as pancreatic cancer, into “hot” tumors (i.e., sensitizing them to immune check point inhibitors). BL-8040-mediated inhibition of the CXCR4-CXCL12 (SDF-1) axis has also shown robust mobilization of HSCs for transplantation in hematological malignancies.

BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About BioLineRx
BioLineRx is a clinical-stage biopharmaceutical company focused on multiple oncology indications. The Company's lead program, BL-8040, is a cancer therapy platform currently being evaluated in a Phase 2a study in 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 hematopoietic cell 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 evaluated 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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