BioLineRx Announces Initiation of Phase 1b/2 Trial for BL-8040 in AML Under Immunotherapy Collaboration

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The BATTLE trial will investigate the combination of BL-8040 and atezolizumab under cancer immunotherapy collaboration

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BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today the initiation of a Phase 1b/2 trial for BL-8040 in combination with atezolizumab (TECENTRIQ®), an anti-PDL1 cancer immunotherapy from Genentech, a member of the Roche Group. The trial, known as the BATTLE study (NCT03154827), will focus on the maintenance treatment of patients with intermediate and high-risk acute myeloid leukemia (AML) who have achieved a complete response (CR) following induction and consolidation therapy.

Up to 60 patients are planned to be enrolled in this multicenter, single arm, open-label study, to evaluate the relapse-free survival, minimal residual disease status, safety and tolerability of the combination of BL-8040 and atezolizumab for maintenance treatment in AML patients. The study's primary endpoint is to assess whether the combination of BL-8040 and atezolizumab prolongs relapse free survival. In addition, the effect of the combination therapy on minimal residual disease, multiple immunological parameters and potential biomarkers will be evaluated. The trial is planned to take place at approximately 22 sites in the U.S., Europe and Israel.

The BATTLE study is a part of BioLineRx's cancer immunotherapy collaboration with Genentech to conduct several Phase 1b/2 studies investigating the combination of BL-8040 with atezolizumab in multiple cancer indications, announced in September 2016.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "We are excited to commence yet another clinical study under this significant immuno-oncology collaboration, following the recent initiation of a study to evaluate the combination of the same two drugs for the treatment of pancreatic cancer. The BATTLE study is the first study under our collaboration in hematologic malignancies, and we are hopeful that combining atezolizumab with BL-8040 will demonstrate the potential to establish a new treatment for AML patients that would extend the duration of remission following induction treatment, in particular for patients for whom stem-cell transplantation is inappropriate. We look forward to the initiation of additional combination studies under this collaboration, all planned by the end of this year."

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown, in a successful Phase 2a study in relapsed and refractory AML patients, to be a robust mobilizer of immune and tumor cells and to be effective in inducing direct tumor cell death.

These two effects, when combined with atezolizumab-induced blockade of the interaction between PD-L1 with PD-1 and B7.1, are hypothesized to have a beneficial effect on the minimal residual disease (MRD) status of AML patients. Specifically, this combined approach could potentially reduce an AML patient's MRD status from positive to negative, and possibly have a favorable effect on disease outcome. This study's regimen aims at further prolonging the period of remission, exploring a novel maintenance approach to these patients.

About BL-8040

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and stem cell mobilization. It functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of 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 from the bone marrow, thereby sensitizing these cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing cell death (apoptosis). In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, T, B and NK cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About Acute Myeloid Leukemia (AML)

Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. According to the American Cancer Society, approximately 20,000 new cases of AML were diagnosed in the United States in 2016, and the median age of AML patients was 67 years old. The first treatment line for patients with AML includes a combination of chemotherapy drugs and is called induction treatment. The median survival for AML patients receiving induction chemotherapy is less than two years, with shorter survival for patients over the age of 60 or for those with certain gene or chromosome aberrations. Due to relapsed or refractory disease (where the disease is not responsive to standard treatments), the overall five-year survival rate for AML is between 10 and 40 percent.

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. 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 is expected to initiate a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is expected to initiate a first-in-man study in the first half of 2018. 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 (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; 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.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

For additional information on BioLineRx, please visit the Company's website at http://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 23, 2017. 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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