BioLineRx Presents Final Results from Phase 2a Trial for Relapsed/Refractory AML at SOHO Conference

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Combination of BL-8040 with Ara-C in difficult-to-treat patient population demonstrated substantial improvement over clinical response rates historically achieved with Ara-C

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BioLineRx Ltd. (NASDAQ/TASE: BLRX) announced that the successful final results of BL-8040's Phase 2a clinical trial in relapsed or refractory acute myeloid leukemia (r/r AML) were presented yesterday evening at the 4th Annual Meeting of the Society of Hematologic Oncology (SOHO), being held September 7-10, 2016, in Houston, Texas.

BL-8040, BioLineRx's lead oncology platform, is a short cyclic peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. The Phase 2a study assessed the efficacy of BL-8040, as a single agent and in combination with Cytarabine (Ara-C), for the treatment of r/r AML. The reported data set includes 45 patients. The majority of patients in the study were heavily pretreated, with 45% of patients being refractory to one or two remission induction treatments, 19% of patients having relapsed after a short first remission of less than 12 months, and 17% of patients having undergone two or more relapses. In addition, the treated patient population included patients that had relapsed post allogeneic stem-cell transplantation (17%), as well as secondary AML patients (24%), both conditions which represent difficult-to-treat populations with poor prognoses.

Results show that treatment with BL-8040 in combination with Ara-C was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg. Response to treatment was associated with efficient CXCR4 inhibition, resulting in high mobilization of blasts and induction of their differentiation. The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). In the 1.5 mg/kg dose selected for the expansion phase of the study (n=22), the composite complete remission rate was 41%. These response rates are superior to the historical response rate of approximately 20% reported for high-risk AML patients treated with Ara-C alone.

In addition, the ongoing follow-up of patients participating in the study's expansion phase and responding to the combination treatment suggests long durability of the remissions achieved, with two-thirds of these patients still alive, based on a follow-up period to date of up to 12 months.

Philip Serlin, Chief Financial and Operating Officer of BioLineRx, commented, "The results from this study clearly confirm the anti-leukemic activity of BL-8040 and reinforce our interest in the AML space. The data demonstrate that sustained inhibition of the CXCR4-CXCL12 axis with BL-8040 is safe and well tolerated, and when given in combination with Ara-C, improves the response rate historically achieved with Ara-C alone. In addition, treatment with BL-8040 as a single agent rapidly and efficiently induces mobilization, differentiation and cell death of AML cells. This selective effect on chemotherapy-resistant cells may be translated into reduction of residual disease, thus pointing to incorporation of BL-8040 into earlier AML treatment lines."

"As previously reported, we are currently in the midst of a large, randomized, controlled, Phase 2b study in the AML consolidation treatment line. In light of the data seen in the Phase 2a study, we have been allocating additional resources to this Phase 2b study. In this regard, we have recently engaged an additional AML research group to participate in the study, and last month we met with regulatory authorities to discuss the development pathway towards registration for this treatment line. In addition, yesterday we announced a significant new cancer immunotherapy collaboration with Genentech, which includes, among other studies, a Phase 1b study in the AML maintenance treatment line. This new study emphasizes our commitment to further develop BL-8040 as a treatment for AML and validates the anti-leukemic effect of BL-8040 seen in the Phase 2a study," concluded Mr. Serlin.

About BL-8040

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. 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 apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and T, B and NK cells. 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 dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds, primarily from academic institutions and biotech companies based in Israel, 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 has recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. 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) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and has recently signed 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 studies for multiple solid tumor indications and AML.

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, including specifically those related to the development and commercialization of BL-8040, 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 10, 2016. 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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