



BioLineRx to Present Overall Survival Data at EHA from Phase 2a Study of BL-8040 in r/r AML Patients

May 17, 2018

BL-8040 in combination with Cytarabine showed significantly improved overall survival compared to historical data

TEL AVIV, Israel, May 17, 2018 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that it will present data at the [23rd Annual Congress of the European Hematology Association \(EHA\)](#), to be held June 14-17, 2018 in Stockholm, Sweden, showing that BL-8040, combined with high dose cytarabine (HiDAC), significantly enhanced overall survival of difficult-to-treat relapsed or refractory AML (r/r AML) patients in a Phase 2a clinical trial.

The Phase 2a study consisted of 42 patients in two cohorts: dose-escalation (range 0.5-2.0 mg/kg) and dose-expansion at the selected dose of 1.5 mg/kg. Patients with r/r AML were treated daily with BL-8040 monotherapy for two days followed by combined administration of BL-8040 and HiDAC for 5 days for 1-2 cycles. Efficacy endpoints included response rate (CR/CRi), overall survival, duration of response and event free survival. BL-8040 in combination with HiDAC was safe and well tolerated at all BL-8040 dose levels (range 0.5-2.0 mg/kg). The response rate for all dosing levels was 29% and median overall survival was 9.1 months, compared with historical data on overall survival of 6.1 months for HiDAC alone. In patients receiving the dose selected for expansion (n=23), the response rate was 39% and median overall survival was 9.2 months with 1-year and 2-year survival rates of 31.6% and 21.1%, respectively. Furthermore, median overall survival for responding patients (CR/CRi) at the 1.5 mg/kg dose was 16.7 months, with 1- and 2-year survival rates of 50% and 37.5%, respectively.

"We are extremely encouraged with the overall survival data continuing to flow from this proof-of-concept study. The study included a very difficult-to-treat patient population, in which 81% were either refractory to one or two inductions, or experienced progression-free survival of less than 12 months after first-line therapy. These data continue to give us confidence in the AML space, where we have two important studies ongoing - a large, randomized controlled Phase 2b study in consolidation AML, and a Phase 1b/2 study in maintenance AML under our collaboration with Genentech," said Philip A. Serlin, Chief Executive Officer of BioLineRx.

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 and immune-cells from the bone marrow, thereby sensitizing cancer cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing cell death (apoptosis) and mobilizing immune-cells. 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 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 has initiated 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 mid-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 is carrying out 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.

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 6, 2018. 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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