



BioLineRx Presents New Overall Survival Data From Phase 2a Study for BL-8040 in r/r AML Patients

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Data presented at EHA shows significantly improved overall survival compared to historical data

Potential biomarker identified for future patient selection, based on statistically significant correlation between responders and levels of AML blast mobilization to peripheral blood

TEL AVIV, Israel, June 18, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that new data presented at the 23rd Annual Congress of the European Hematology Association (EHA), held in Stockholm, Sweden, shows that BL-8040, combined with high dose cytarabine (HiDAC), significantly enhanced overall survival in difficult-to-treat relapsed or refractory AML (r/r AML) patients in a Phase 2a clinical trial. In addition, an important new finding shows a statistically significant correlation between patient response and the mobilization of AML blasts. Responding patients demonstrated a clear and significant increase in the number of AML blasts in the peripheral blood following BL-8040 treatment, whereas non-responding patients were largely unaffected.

"We are extremely pleased to see further significant improvement in overall survival for this very difficult-to-treat patient population, as data continues to accumulate from our Phase 2a proof-of-concept study in relapsed or refractory AML," stated Philip A. Serlin, Chief Executive Officer of BioLineRx. "In addition, exciting new findings indicate a clear correlation between patient response and mobilization of AML blasts, thus identifying a potential biomarker for selecting patients likely to respond to BL-8040. These encouraging results strongly support the continued development of BL-8040 in relapsed or refractory AML, giving BioLineRx broad therapeutic coverage in the AML space, with potential activity at different stages of the disease and in different patient populations. We look forward to providing additional updates on overall survival from this study, and continue to execute on our other two important AML trials currently ongoing – a large, randomized, controlled Phase 2b study in consolidation AML, and a Phase 1b/2 study in maintenance of AML under our collaboration with Genentech," added Mr. Serlin.

The Phase 2a study consisted of 42 patients in two cohorts: (i) dose-escalation (range 0.5-2.0 mg/kg) and (ii) 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 1.5 mg/kg dose selected for expansion (n=23), the response rate was 39% and median overall survival was 10.7 months with 1-year, 2-year and 3-year survival rates of 38.1%, 23.8% and 23.8%, respectively. Furthermore, median overall survival for responding patients at the 1.5 mg/kg dose (n=9) was 21.8 months, with 1-year, 2-year and 3-year survival rates of 66.7%, 44.4% and 44.4%, respectively. Responding patients also demonstrated a statistically significant mean 6.3-fold increase (p=0.003) in the number of AML blasts in the peripheral blood following BL-8040 monotherapy treatment, whereas in non-responding patients the mean-fold increase was minor and non-significant (1.66-fold; p=0.21).

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). In addition, BL-8040 has also demonstrated robust mobilization of other cell types, including the mobilization of hematopoietic stem and progenitor cells, T, B, NK and antigen presenting 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 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.

Contact:

PCG Advisory
Vivian Cervantes
Investor Relations
+1-646-863-6274
vivian@pcgadvisory.com

Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsjihai5@gmail.com

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