



## BioLineRx Reports Overall Survival Results From Long-term Follow-up of Phase 2a Trial in r/r AML

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### BL-8040 in combination with high-dose Ara-C significantly improved overall survival compared to historical data

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BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today positive overall survival data from the long-term follow-up part of the Phase 2a trial of BL-8040 for the treatment of relapsed or refractory acute myeloid leukemia (r/r AML). The results demonstrate that the combination of BL-8040 with high-dose Ara-C (HiDAC) in this difficult-to-treat patient population significantly improved overall survival, compared with historical data of HiDAC monotherapy.

The long-term survival results from the Phase 2a study derive from the expansion phase of the study, which included 16 patients (out of 42 total patients enrolled in the study). Participants were treated with BL-8040 as a monotherapy for two days, followed by a combination of BL-8040 and HiDAC for 5 days. The mean follow-up time was 338 days (29-853 days). BL-8040 in combination with HiDAC was found to be safe and well tolerated, and the response rate was 38% (6/16). Median overall survival was 11.1 (1-28) months, the estimated one-year survival rate was 37.5% and the estimated two-year survival rate was 28.5%, compared to historical data for patients treated only with HiDAC showing overall survival of approximately 6.1 months. Furthermore, the subset of patients exhibiting a response showed prolonged overall survival, with estimated one-year and two-year survival rates of 60%. Median overall survival for this group could not be calculated, since only two of these patients have relapsed.

The Phase 2a study assessed the efficacy of BL-8040, as a single agent and in combination with HiDAC, for the treatment of r/r AML. The majority of patients in the study were heavily pre-treated, and the treated patient population included patients who had relapsed following allogeneic stem-cell transplantation, as well as secondary AML patients - both conditions which represent difficult-to-treat populations with poor prognoses. Top-line results from the full study (n=42) were previously reported in March 2016, and showed an overall response rate (CR+CRi) of 38%, compared with historical data relating to HiDAC of approximately 20%.

Philip Serlin, Chief Executive Officer of BioLineRx, commented, "We are very pleased from the long-term follow-up results of this study, which continue to demonstrate the robust anti-leukemic activity of BL-8040 and show that combined treatment with HiDAC not only increases the response rate, but also increases overall survival time compared to historical data. We will continue to monitor the overall long-term survival of patients in this study, as we progress in the execution of our two other important studies in AML - our Phase 2a study in maintenance AML, which is part of our collaboration with Genentech, and our Phase 2b study in consolidation AML. The promising survival and response results we have seen in the r/r AML study, along with the future data readouts from the additional studies we're currently running in this disease, have the potential to make BL-8040 a key player in the AML setting."

#### 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 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 (tradename of Merck & Co., Inc.), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and MSD'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 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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