



BioLineRx Announces Initiation of Phase 3 GENESIS Trial in Stem-Cell Mobilization for Autologous Transplantation in Multiple Myeloma Patients

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Study will assess mobilization of hematopoietic stem cells by BL-8040 compared to placebo, on top of G-CSF, for autologous transplantation in multiple myeloma patients

TEL AVIV, Israel, December 21, 2017 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today initiation of the Phase 3 GENESIS clinical trial, in which BL-8040 will be compared to placebo, on top of granulocyte colony-stimulating factor (G-CSF), for the mobilization of hematopoietic stem cells (HSCs) used for autologous transplantation in multiple myeloma patients.

The GENESIS study is a Phase 3, randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability and efficacy of BL-8040 and G-CSF, compared to placebo and G-CSF, for the mobilization of HSCs for autologous transplantation in multiple myeloma patients. The study will commence with a lead-in period for dose confirmation, which will include 10-30 patients, and progress to the placebo-controlled main part, which is designed to include 177 patients in more than 15 centers. Treatment will include 5-8 days of G-CSF, with a single dose of BL-8040 or placebo on day 4. Apheresis for stem cell collection will be performed on day 5. Further apheresis sessions may be conducted if needed in order to reach the benchmark of $\geq 6 \times 10^6$ mobilized HSCs.

The primary objective of the study is to demonstrate that BL-8040 on top of G-CSF is superior to G-CSF alone in the ability of mobilize $\geq 6 \times 10^6$ HSCs in up to 2 aphereses. Secondary objectives include time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "The initiation of our first Phase 3 trial for BL-8040 is an important milestone in the robust development plan of our lead oncology platform. Treatment with BL-8040 as a single administration and up-to-two-day collection regimen for rapid mobilization of stem cells could represent a significant improvement over the current treatment, which requires up to four apheresis sessions. We look forward to top-line results from the study expected in 2020."

Dr. John F. DiPersio, Chief, Division of Oncology at the Washington University School of Medicine, and lead investigator of the study, stated, "I am very excited to test the role of BL-8040, a novel CXCR4 inhibitor with G-CSF for the mobilization of peripheral blood stem cells from patients undergoing autologous transplant for multiple myeloma. I am hopeful that this will provide another approach to the optimal hematopoietic stem cell collection in this challenging group of patients".

About BL-8040

BL-8040 is a short peptide for the treatment of stem cell mobilization, acute myeloid leukemia and solid tumors. BL-8040 has demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, T, B and NK cells. It functions as a high-affinity antagonist for CXCR4, with long receptor occupancy. 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. 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 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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