



## BioLineRx Announces Regulatory Submission of Phase 3 Registrational Study for BL-8040 in Stem Cell Mobilization

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**- GENESIS is a Phase 3 trial for the mobilization of hematopoietic stem cells for autologous transplantation in patients with multiple myeloma -**  
**- Initiation of study expected by end of 2017 -**

TEL AVIV, Israel, Aug 21, 2017 /PRNewswire/ --BioLineRx Ltd. (NASDAQ: BLRX) (TASE:BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today the filing of regulatory submissions required to commence a randomized, controlled Phase 3 registrational trial of BL-8040 for the mobilization of hematopoietic stem cells for autologous transplantation in patients with multiple myeloma. The trial, named GENESIS, is expected to commence by the end of 2017, following receipt of regulatory approvals.

The Phase 3 GENESIS trial is aimed at evaluating the safety, tolerability and efficacy of the combination treatment of BL-8040 and granulocyte colony-stimulating factor (G-CSF), as compared to the control arm of placebo and G-CSF. The trial will be conducted in two parts: The first part, designed to validate the optimal dosing of BL-8040, is a lead-in, open-label, multi-center study that will include 10-30 patients, in order to assess the efficacy and safety of treatment with BL-8040 and G-CSF. This part will be followed by a randomized, placebo-controlled, multi-center study in approximately 180 patients. The primary endpoint will be the proportion of subjects mobilizing  $\geq 6.0 \times 10^6$  CD34+ cells/kg with up to 2 apheresis sessions in preparation for autologous transplantation after a single administration of BL-8040 and G-CSF, as compared to placebo and G-CSF.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "We are excited to move forward with BL-8040 into a Phase 3 registration study. We have previously reported positive results supporting BL-8040 as a one-day dosing and up-to-two-day collection regimen for rapid mobilization of stem cells. This represents a significant improvement over the current treatment, which requires four-to-eight daily injections of G-CSF and one-to-four apheresis sessions. We therefore hope that this Phase 3 trial will further support these results and help improve the standard of care for multiple myeloma patients."

"In parallel, we are continuing to expand the potential of our robust BL-8040 oncology platform, by advancing multiple clinical studies for additional indications that are ongoing or expected to commence during 2017. These include a large, randomized, controlled Phase 2b study in AML, as well as several Phase 2 combination studies with immune checkpoint inhibitors in solid tumors and hematological malignancies," added Mr. Serlin.

### 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 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 cell death (apoptosis). 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 Stem Cell Mobilization

High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, as well as various forms of lymphoma and leukemia. Stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), harvested from the peripheral blood by apheresis, and infused to the patient after chemotherapy. This type of treatment often replaces the use of traditional bone marrow transplantation, because the stem cells are easier to collect and the treatment allows for a quicker recovery time and fewer complications.

### 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 (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA<sup>®</sup>; and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's Tecentriq<sup>®</sup> (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](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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View original content: <http://www.prnewswire.com/news-releases/biolinerx-announces-regulatory-submission-of-phase-3-registrational-study-for-bl-8040-in-stem-cell-mobilization-300506916.html>

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