



## BioLineRx to Initiate Phase 3 Study with BL-8040 as Novel Stem Cell Mobilization Treatment Following Successful Meeting with FDA

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**- Initiation of Phase 3 registrational study expected in second half of this year**

**- Study to focus on stem cell mobilization for autologous transplantation in multiple myeloma patients**

BioLineRx Ltd. (NASDAQ/TASE: BLRX, BLRX.TA), a clinical-stage biopharmaceutical company focused on oncology and immunology, today announced that it has met with the U.S. Food and Drug Administration (FDA) and has gained clarity on the development program and the design of a Phase 3 pivotal study for BL-8040, its robust platform for multiple oncology indications, as a novel stem cell mobilization treatment for autologous bone-marrow transplantation. Following its successful meeting with the FDA, the Company anticipates the initiation of a registrational Phase 3 trial during the second half of 2017. The study will investigate BL-8040 in combination with granulocyte colony-stimulating factor (G-CSF) for mobilization of stem cells from the bone marrow to the peripheral blood, followed by collection and subsequent autologous transplantation in patients with multiple myeloma.

"BL-8040 given as a single injection in a Phase 1/2 study in multiple myeloma patients was previously shown to be highly effective in mobilizing stem cells in combination with G-CSF," said Philip Serlin, Chief Executive Officer of BioLineRx. "Following our recent successful meeting with the FDA, we believe we have a clear development path forward towards registration of BL-8040 as a novel stem cell mobilization treatment for autologous transplantation. We look forward to the initiation of the Phase 3 pivotal study later this year, which, if successful, could pave the way for future commercialization of BL-8040."

"We see clear potential for BL-8040 to benefit multiple myeloma patients undergoing autologous bone marrow transplantation. In parallel, we are continuing to expand the potential of our unique BL-8040 oncology platform, with multiple clinical studies for additional indications that are up and running or expected to commence during 2017. These include several combination studies with immune checkpoint inhibitors, a Phase 2b study in consolidation AML and a Phase 2 study in allogeneic stem-cell mobilization as a monotherapy with topline results expected by the end of 2017," 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 apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and 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 acute myeloid leukemia (AML) and is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 2 study in stem cell mobilization for allogeneic 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 Pharma AG 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®; and a collaboration agreement with Genentech Inc., a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's Atezolizumab in several Phase 1b 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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