# BioLineRx Provides Update on Phase 2 Open-Label Study for BL-8040 as Novel Stem Cell Mobilization Treatment

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***- Results to date confirm that single injection of BL-8040 mobilizes sufficient amounts of cells required for allogeneic transplantation without need for G-CSF -***

***- Top-line results expected by end of 2017 -***

BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, reported partial results data from its open-label Phase 2 trial for BL-8040 as a novel monotherapy approach for the mobilization and collection of blood forming stem and progenitor cells from the peripheral blood.

The study consists of donor and patient pairs for allogeneic hematopoietic cell transplantation. The first part of the study, which is nearing completion, is intended to enroll an initial cohort of 10 donor and recipient pairs, consisting of patients with advanced hematological malignancies and their HLA-matched sibling donors. Interim results show that a single injection of BL-8040 mobilized sufficient amounts of cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care. Furthermore, all recipients transplanted so far have experienced a successful neutrophil engraftment. The recipients will be followed for one year to assess acute and chronic GVHD events. As for the donors, BL-8040 treatment was safe and well tolerated.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "We are very encouraged by these initial results of the Phase 2 clinical trial for assessing BL-8040, our lead oncology and hematology platform, as a single agent for hematopoietic stem cell mobilization for allogeneic transplantation. Hematopoietic stem cells are increasingly used as part of the treatment regimen for certain types of hematological cancers, as well as for severe anemia and immune deficiency disorders. These results, supporting BL-8040 as a one-day dosing and up-to-two-day collection regimen, for rapid mobilization of substantial amounts of stem cells, represent a significant improvement over the current standard of care, which requires four-to-six daily injections of G-CSF and one-to-four apheresis sessions. If there are no safety concerns regarding graft failure or rejection after the interim safety review of donor-recipient pairs participating in Part 1 of the study, we will continue with Part 2 of the study, which will permit enrollment of recipients with either matched sibling or haploidentical donors, up to a total enrollment in the study of 24 donor-recipient pairs. We are looking forward to the topline results expected by the end of 2017."

"We continue our efforts to maximize the potential of our unique BL-8040 oncology platform, with multiple clinical studies for additional indications up and running or expected to start in 2017, including several combination studies with immune checkpoint inhibitors and a registration study in stem-cell mobilization for autologous transplantation," added Mr. Serlin.

The Phase 2 open-label study is conducted in collaboration with the Washington University School of Medicine, Division of Oncology, and will enroll up to 24 donor/recipient pairs, aged 18-70. The trial is designed to evaluate the ability of BL-8040, as a single agent, to promote stem cell mobilization for allogeneic hematopoietic cell transplantation. On the donor side, the primary endpoint of the study is the ability of a single injection of BL-8040 to mobilize sufficient amounts of cells for transplantation following up to two apheresis procedures. On the recipient side, the study aims to evaluate the time to engraftment rate following transplantation of the BL-8040 collected graft.

The study will also evaluate the safety and tolerability of BL-8040 in healthy donors, as well as graft durability, the incidence of grade 2-4 acute and chronic GVHD, and other recipient related parameters in patients who have undergone transplantation of hematopoietic cells mobilized with BL-8040.

**About BL-8040**

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. 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 hematopoietic 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. Modern peripheral stem-cell harvesting often replaces the use of traditional surgical bone marrow stem-cell harvesting. In the modern method, stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), often with the addition of a mobilizing agent such as Plerixafor (Mozobil), harvested from the donor's peripheral blood by apheresis, and infused to the patient after chemotherapy ablation treatment.

An allogeneic hematopoietic cell transplant involves matching a patient's tissue type, specifically their human leukocyte antigen (HLA) tissue type, with that of a related or unrelated donor. HLA proteins are found on all cells of our body and are the main way the immune system tells the difference between our own cells and foreign cells. The closer the HLA match between a donor and recipient, the greater the chance a transplant will be successful. If the HLA match is not close enough, the donor's immune system, which accompanies the donated stem cells, recognizes the HLA mismatch, and will attack the recipient's tissues. This process is known as graft versus host disease (GVHD).

Approximately 70% of people with a hematological malignancy or bone marrow failure syndrome who need an allogeneic transplant have an

HLA-identical sibling or unrelated donor available. For patients who need a stem cell transplant but do not have an HLA-matched related or unrelated donor, recent medical advances have made possible the use of a partially matched or haploidentical related donor. A haploidentical related donor is usually a 50% match to the recipient and may be the recipient's parent, sibling or child.

The advantage of having a haploidentical transplant is that it increases the chance of finding a donor as almost everyone has at least one haploidentical relative. Relatives can usually be asked to donate stem cells much more quickly than unrelated volunteer donors, particularly when the volunteer donors live in other countries, thereby allowing transplants to be done in a more timely manner.

With improvements in medical treatment, complications of a haploidentical transplant, such as GVHD, rejection of the graft and slow recovery of the immune system appear not to be increased compared to transplants using HLA-matched related or unrelated donors. Since this is a relatively new approach to stem cell transplantation, a haploidentical transplant is a treatment option that is not offered at all treatment centers, but is becoming more common.

**About BioLineRx**

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds, primarily from academic institutions and biotech companies based in Israel, 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 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 BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. 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®; 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 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 10, 2016. 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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