



## BioLineRx Announces an Oral Presentation and Three Poster Presentations at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition

November 4, 2021

- Oral presentation highlights successful GENESIS Phase 3 pivotal trial of Motixafortide plus G-CSF for stem cell mobilization in multiple myeloma patients -
- Presentations include data showing the addition of Motixafortide to G-CSF rapidly mobilizes large numbers of specific stem cells, which may contribute to shorter engraftment time when infused in high numbers -

TEL AVIV, Israel, Nov. 4, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical Company focused on oncology, today announced an oral presentation and three poster presentations at the 63<sup>rd</sup> American Society of Hematology (ASH) Annual Meeting & Exposition, which is being held December 11-14, 2021 in Atlanta, GA, and virtually.

The oral presentation will elaborate on the successful results of the Company's GENESIS Phase 3 pivotal trial. The study showed highly significant and clinically meaningful results supporting the use of Motixafortide on top of G-CSF for mobilization of stem cells for subsequent collection and transplantation in patients with multiple myeloma. In addition, the poster presentations will show that extended inhibition of the CXCR4 receptor by Motixafortide results in the mobilization of high numbers of stem cells, including specific sub-populations, which were correlated with reduced time to engraftment when infused in high numbers.

The Company is also presenting findings from in-vivo and in-vitro pre-clinical studies demonstrating that Motixafortide acts as an immunomodulator by affecting the biology of regulatory T cells (Tregs), supporting biomarker findings from the Company's COMBAT Phase 2 study in pancreatic cancer patients.

"We are very pleased with the breadth of our oral and poster presentations at this year's ASH meeting, which reflect the versatility of Motixafortide as the potential backbone of promising new treatments for both hematological and solid tumor cancers," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Of particular note is the oral presentation on the outstanding results from our GENESIS Phase 3 pivotal study in stem cell mobilization demonstrating that Motixafortide effectively mobilizes a high number of cells enabling ~90% of patients to undergo transplantation following a single administration of Motixafortide and a single apheresis session. In addition, the high number of cells mobilized by Motixafortide enables infusion of an optimal number of cells, which could result in faster time to engraftment, and also allows for cryopreservation for future transplantation(s). These results, together with our recently completed successful pharmacoeconomic study, strongly support our view that Motixafortide on top of G-CSF can become the new standard of care in SCM, if approved, to the benefit of patients and payers alike. We look forward to submitting an NDA in the first half of next year, as previously communicated."

Further details of the presentations are provided below.

### Oral Presentation

**Title: Motixafortide (BL-8040) and G-CSF Versus Placebo and G-CSF to Mobilize Hematopoietic Stem Cells for Autologous Stem Cell Transplantation in Patients with Multiple Myeloma: The GENESIS Trial**

Date: Sunday, December 12, 2021

Time: 12:00 PM

Location: Georgia World Congress Center, Hall A1

This oral presentation describes the GENESIS Phase 3 pivotal trial design, endpoints and results. The GENESIS study was a double blind, placebo controlled, multicenter trial, in which 122 patients were randomized (2:1) to receive either Motixafortide + G-CSF or placebo + G-CSF for stem cell mobilization prior to stem cell transplant in multiple myeloma patients. Total CD34+ cells/kg were analyzed on site to determine if patients mobilized to the goal and all samples were subsequently sent for assessment by a central laboratory. The number of CD34+ cells infused was determined independently by each investigator according to local practice.

The study concluded that a single administration of Motixafortide on top of G-CSF significantly increased the proportion of patients mobilizing  $\geq 6 \times 10^6$  CD34+ cells/kg for stem cell transplantation (92.5%) vs G-CSF alone (26.2%) in up to two apheresis days ( $p < 0.0001$ ), while enabling 88.8% to collect  $\geq 6 \times 10^6$  CD34+ cells/kg in just one apheresis day (vs 9.5% with G-CSF alone;  $p < 0.0001$ ). In addition, the median number of hematopoietic stem cells mobilized in one apheresis day with Motixafortide + G-CSF was  $10.8 \times 10^6$  CD34+ cells/kg vs  $2.1 \times 10^6$  CD34+ cells/kg with G-CSF alone.

### Poster Presentations

**Title: Autologous Hematopoietic Cell Transplantation with Higher Doses of CD34+ Cells and Specific CD34+ Subsets Mobilized with Motixafortide and/or G-CSF is Associated with Rapid Engraftment – A Post-hoc Analysis of the GENESIS Trial**

Date: Sunday, December 12, 2021

Time: 6:00 PM - 8:00 PM

The CD34+ hematopoietic stem and progenitor cell (HSPC) dose infused during stem cell transplantation remains one of the most reliable clinical parameters to predict quality of engraftment. A minimum stem cell dose of  $2-2.5 \times 10^6$  CD34+ cells/kg is considered necessary for reliable engraftment, while optimal doses of  $5-6 \times 10^6$  CD34+ cells/kg are associated with faster engraftment, as well as fewer transfusions, infections, and antibiotic days.

An analysis was performed using pooled data from all patients in the GENESIS trial to evaluate time to engraftment based on the total number of CD34+ cells/kg infused, as well as specific numbers of CD34+ cell sub-populations infused.

The addition of Motixafortide to G-CSF enabled significantly more CD34+ cells to be collected in one apheresis (median  $10.8 \times 10^6$  CD34+ cells/kg) compared to G-CSF alone ( $2.1 \times 10^6$  CD34+ cells/kg), as well as 3.5-5.6 fold higher numbers of hematopoietic stem cells (HSCs), multipotent progenitors (MPPs), common myeloid progenitors (CMPs) and granulocyte and macrophage progenitors (GMPs) (all p-values <0.0004). A dose response was observed with a significant correlation between faster time to engraftment and infusion of higher number of total CD34+ HSPC doses ( $\geq 6 \times 10^6$  CD34+ cells/kg) and combined HSC, MPP, CMP and GMP subsets. The high number of CD34+ cells/kg mobilized with Motixafortide on top of G-CSF enables the potential infusion of  $\geq 6 \times 10^6$  CD34+ cells/kg, as well as cryopreservation of cells for later use.

**Title: Immunophenotypic and Single-Cell Transcriptional Profiling of CD34+ Hematopoietic Stem and Progenitor Cells Mobilized with Motixafortide (BL-8040) and G-CSF Versus Plerixafor and G-CSF Versus Placebo and G-CSF: A Correlative Study of the GENESIS Trial**

Date: Monday, December 13, 2021

Time: 6:00 PM - 8:00 PM

CD34 expression remains the most common immunophenotypic cell surface marker defining human hematopoietic stem and progenitor cells (HSPCs). The addition of CXCR4 inhibitors to G-CSF has increased mobilization of CD34+ HSPCs for stem cell transplantation; yet the effect of CXCR4 inhibition, with or without G-CSF, on mobilization of specific immunophenotypic and transcriptional CD34+ HSPC subsets is not well-characterized.

Motixafortide is a novel cyclic peptide CXCR4 inhibitor with a low receptor-off rate and extended in vivo action when compared to plerixafor. GENESIS Phase 3 trial patients were prospectively randomized (2:1) to receive either Motixafortide + G-CSF or placebo + G-CSF for HSPC mobilization. Demographically similar multiple myeloma patients undergoing mobilization with plerixafor + G-CSF prior to stem cell transplant were prospectively enrolled in a separate tissue banking protocol.

Extended CXCR4 inhibition with Motixafortide + G-CSF mobilized significantly higher numbers of combined CD34+ HSCs, MPPs and CMPs compared to plerixafor + G-CSF or G-CSF alone (p<0.05). Additionally, Motixafortide + G-CSF mobilized a 10.5 fold higher number of immunophenotypically primitive CD34+ HSCs capable of broad multilineage hematopoietic reconstitution compared to G-CSF alone (p<0.0001) and similar numbers compared to plerixafor + G-CSF. Furthermore, lack of CXCR4 inhibition resulted in mobilization of more-differentiated HSCs, whereas extended CXCR4 inhibition with Motixafortide + G-CSF (but not plerixafor + G-CSF) mobilized a unique MPP-III subset expressing genes specifically related to leukocyte differentiation.

**Title: The High Affinity CXCR4 Inhibitor, BL-8040, Impairs the Infiltration, Migration, Viability and Differentiation of Regulatory T Cells**

Date: Sunday, December 12, 2021

Time: 6:00 PM - 8:00 PM

This poster describes results of pre-clinical in-vivo and in-vitro studies demonstrating that Motixafortide potentially acts as an immunomodulator by affecting the biology of regulatory T cells. Motixafortide reduced the amount of infiltrating Tregs into the tumors, impaired the migration of Tregs toward CXCL12 and induced Tregs cell death. Furthermore, Motixafortide was found to inhibit the differentiation of naïve CD4 T cells toward Tregs.

**About BioLineRx**

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

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.

*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. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and*

*its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 February 23, 2021. 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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