BioLineRx Announces USPTO Allowance of New Composition of Matter Patent on Motixafortide

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– Allowance strengthens company's intellectual property estate and extends motixafortide patent protection in the U.S. through December 2041 –

TEL AVIV, Israel, Oct. 16, 2024 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a patent, titled, "COMPOSITION OF BL-8040," which covers the composition of motixafortide (APHEXDA®/BL-8040). The patent strengthens BioLineRx's robust intellectual property (IP) estate and extends its patent protection on motixafortide in the U.S. through December 2041.

"We are very pleased to significantly strengthen our motixafortide IP with this key Composition of Matter patent that, among other things, extends our protection on this drug substance through December 2041," stated Philip Serlin, Chief Executive Officer of BioLineRx. "We believe this allowance reflects the USPTO's acknowledgment of the unique attributes of motixafortide that make it a significant advancement among mobilization agents for multiple myeloma patients undergoing autologous stem cell transplantation, as well as the other high-need indications in which it is being investigated, including pancreatic cancer and gene therapies for patients with sickle cell disease (SCD)."

In addition to a broad range of U.S. and international patents covering various aspects of motixafortide, including composition of matter, methods of synthesis, methods of use and combinations, BioLineRx was granted seven years of Orphan Drug market exclusivity beginning on September 8, 2023, the day APHEXDA® (motixafortide) was approved by the FDA, in combination with G-CSF, for use by multiple myeloma patients undergoing autologous stem cell transplantation. Additionally, motixafortide was granted five years of data exclusivity across all indications as a New Chemical Entity (NCE). The NCE exclusivity also commenced on September 8, 2023.

Motixafortide has also been granted Orphan Drug Designation in the U.S. and Europe for the treatment of pancreatic cancer, as well as in the U.S. for the treatment of acute myeloid leukemia (AML).

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company's first approved product is APHEXDA® (motixafortide) with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma. BioLineRx is advancing a pipeline of investigational medicines for patients with sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., the company is driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

Forward Looking Statement

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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, the potential benefits of APHEXDA, the ongoing commercialization of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of APHEXDA, as well as potential investigational uses of motixafortide. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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: clinical development, commercialization and market acceptance of our therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; 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; whether BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; whether the clinical trial results for APHEXDA will be predictive of real-world results; 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, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; BioLineRx's ability to establish, operationalize 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 and ability to access sufficient additional financing, including any unexpected costs or delays in the commercial launch of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of Israel's war with Hamas, Hezbollah and other terrorist organizations, which may exacerbate the magnitude of the factors discussed above. 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 26, 2024. 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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