



BioLineRx Strengthens Intellectual Property Estate with Notice of Allowance for U.S. Patent Covering Method of Manufacturing Motixafortide (BL-8040) Suitable for Large Scale Production

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- New patent, when issued, will be valid until December 2041 -

- Additional IP complements U.S. market exclusivity awarded to BioLineRx upon FDA approval of APHEXDA® (motixafortide) in September 2023 as a result of its Orphan Drug and New Chemical Entity designations -

TEL AVIV, Israel, March 4, 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, "Process for Manufacturing Peptide," covering a method of manufacturing motixafortide (BL-8040) that is suitable for large scale production.

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 market exclusivity *across all indications* as a New Chemical Entity (NCE). The NCE exclusivity also commenced on September 8, 2023.

"This is a very meaningful addition to our IP portfolio as we look to scale up the production of motixafortide to support both the commercial demand for APHEXDA for stem cell mobilization in multiple myeloma patients as well as the numerous ongoing clinical trials underway in other indications, including metastatic pancreatic cancer and for gene therapies in sickle cell disease," stated Philip Serlin, Chief Executive Officer of BioLineRx. "When combined with the seven years of Orphan Drug Designation market exclusivity that we were granted upon FDA approval of APHEXDA beginning last September, and five years of exclusivity across all indications as a New Chemical Entity, we have a broad set of IP protections that we believe will allow us to maximize the value of this important molecule for our company and shareholders for years to come."

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," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, expectations and commercial potential of motixafortide, as well as its potential investigational uses. 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: 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 the COVID-19 pandemic, the Russian invasion of Ukraine, the declared war by Israel against Hamas and the military campaigns against Hamas 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 22, 2023. 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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