BioLineRx Announces Receipt of USPTO Notice of Allowance for Key Patent Covering GLIX1 for Treating a Broad Range of Cancer Types

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Patent covers the use of GLIX1 for treating cancers in which cytidine deaminase (CDA) is not over-expressed (representing over 90% of cancers)

Patent further broadens and strengthens GLIX1 patent protection until 2040, with a possible patent-term extension of up to five years

TEL AVIV, Israel, Nov. 17, 2025 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical development stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that the U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for a key patent, entitled, 'Deoxy-Cytidine or Uridine Derivatives for Use in Cancer Therapies' (Pat. Appl. Ser. No. 18/602,969), which covers the use of GLIX1 for treating cancer types in which cytidine deaminase (CDA) is not over-expressed beyond a specific threshold. Corresponding patent applications are pending worldwide. The patent further broadens and strengthens GLIX1's patent protection for the treatment of cancer until 2040, with a possible patent-term extension of up to five years.

It is estimated that over 90% of all cancers do not overexpress CDA beyond the specific threshold, reflecting the importance of this additional intellectual property as BioLineRx expands development of GLIX1 beyond glioblastoma, its initial indication, into other cancer types, once safety and dosing in glioblastoma are established.

"This Notice of Allowance from the USPTO is a critical addition to GLIX1's intellectual property estate, as it protects our opportunity to evaluate this exciting molecule across the majority of cancers," stated Philip Serlin, Chief Executive Officer of BioLineRx. "As we prepare to initiate a first-in-human study of GLIX1 in patients with glioblastoma in the first quarter of 2026, we are in parallel advancing pre-clinical studies in other cancer models. We believe GLIX1, with its unique mechanism of action that targets the DNA damage response in cancer cells, has the potential to offer new hope to patients suffering from a broad range of difficult-to-treat cancers, and we are eager to commence clinical trials early next year."

GLIX1 is covered by a comprehensive portfolio of patents that are both issued and pending. In addition to the allowed U.S. patent referenced above and corresponding patents issued and pending worldwide, GLIX1 is covered by additional issued or pending patents, which broaden the coverage for its use in treating cancer as both monotherapy and in combination with established anti-cancer agents:

- GLIX1 for use in treating cancer of the central nervous system, such as glioblastoma, is covered by patents issued in the US, Europe and 13 other countries. The patents are valid until at least 2040 (with a possible patent term extension of up to five years).
- GLIX1, in combination with PARP inhibitors, for use in treating homologous recombination (HR) proficient cancers, which represent the majority of cancers, is covered by a pending international patent application. Corresponding national-phase patents, if granted, will be valid until at least 2044 (with a possible patent term extension of up to five years).

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The Company's first approved product, APHEXDA® (motixafortide), is indicated in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma, and is being commercialized by Ayrmid Ltd. (globally, except Asia) and Gloria Biosciences (in Asia). BioLineRx has retained the rights to develop motixafortide in metastatic pancreatic cancer (PDAC) and has a Phase 2b PDAC trial currently ongoing under a collaboration with Columbia University.

In addition, BioLineRx has established a joint venture with Hemispherian AS to develop GLIX1, a first-in-class, oral, small molecule targeting DNA damage response in glioblastoma and other cancers, for which a Phase 1/2a clinical trial is expected to be initiated in the first quarter of 2026.

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

Forward Looking Statements

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 of GLIX1. 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 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; 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 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; 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, manage, and maintain corporate collaborations, as well as the ability of BioLineRx's collaborators to execute on their development and commercialization plans; BioLineRx's ability to integrate new therapeutic candidates and new personnel as well as new collaborations; 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; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; BioLineRx's ability to maintain the listing of its ADSs on Nasdaq; and statements as to the impact of the political and security situation in Israel on BioLineRx's business, 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 31, 2025. 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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