



BioLineRx Announces Initiation of Phase 1/2a Study of GLIX1 for the Treatment of Glioblastoma (GBM)

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GLIX1, a TET2 activator, is a first-in-class, oral, small molecule targeting DNA damage response in glioblastoma and other cancers

GLIX1 has demonstrated potent anti-tumor activity in multiple GBM models, excellent blood-brain barrier penetration and a favorable safety profile in preclinical toxicology studies

Study is being conducted by world-leading glioblastoma investigators, led by Dr. Roger Stupp

TEL AVIV, Israel, March 26, 2026 /PRNewswire/ – BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical development stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced the initiation of a first-in-human, Phase 1/2a study of GLIX1 for the treatment of recurrent and progressive GBM and other high-grade glioma (NCT07464925).



GLIX1 is an oral small molecule with a novel mechanism of action applicable to a broad range of cancers. By restoring TET2 activity, GLIX1 selectively targets DNA damage repair in cancer cells only. GBM was selected as the first indication for GLIX1 due to the low level of TET2 activity in this aggressive brain cancer, for which there remains a high unmet medical need for novel and more effective treatments. In extensive preclinical studies, including in-vivo GBM models, GLIX1 demonstrated potent anti-tumor activity and excellent blood-brain-barrier penetration, combined with a favorable safety profile in toxicology studies.

Three renowned academic centers will ultimately participate in this clinical trial. The first center ready to start enrolling patients is NYU Langone Health, led by Dr. Alexandra Miller. This will be followed by Northwestern University, led by Dr. Roger Stupp and Dr. Ditte Primdahl, and by Moffit Cancer Center, led by Dr. Patrick Grogan.

"The initiation of this study represents the culmination of many months of tireless work on behalf of our team and the team of our collaboration partner, Hemispherian AS, as well as a pivotal moment in our mission to identify and advance innovative drugs to treat diseases with significant unmet needs," stated Philip Serlin, Chief Executive Officer of BioLineRx. "GLIX1 has a very compelling profile supporting this Phase 1/2a study and, to that end, we look forward to initial data in the first half of 2027."

Dr. Alexandra Miller, Chief of Neuro-Oncology and Co-Director of the Brain and Spine Tumor Center at the Perlmutter Cancer Center, NYU Langone Health, stated, "I am pleased to be the first investigator able to enroll patients into this critical study, which brings new hope to patients who are in desperate need of innovative and novel treatment options."

Dr. Roger Stupp, Medical Director of the Malnati Brain Tumor Institute at Northwestern University in Chicago, and lead investigator of the study, added, "GLIX1 is a promising innovative molecule with impressive pre-clinical data, and I could not be more excited to participate in this study. The protocol will rigorously assess the safety of an agent with an entirely novel mechanism of action, with the potential to ultimately integrate well and synergize with the current treatments. We urgently need breakthrough innovations for our patients suffering from glioblastoma, one of the most aggressive and difficult malignancies to treat."

Phase 1/2a clinical trial design (NCT07464925)

The Phase 1 part of the trial is expected to recruit up to 30 patients with recurrent and progressive GBM and other high-grade glioma. The objective is to establish a maximum tolerated dose (MTD) and/or a recommended dose based on safety, PK/PD and preliminary efficacy. Data from the Phase 1 part of the trial are anticipated in H1 2027.

The Phase 2a expansion part of the trial is planned to include various population cohorts, including GBM (newly diagnosed and/or recurrent), as well as additional cancers with/without standard of care (e.g., PARP inhibitors). These cohorts are expected to identify preliminary efficacy, PD assessments and dose optimization data, serving as the basis for a rapid and effective advanced clinical development plan.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The Company's lead development asset is GLIX1, a first-in-class, oral, small molecule targeting DNA damage response in glioblastoma and other solid tumors, for which a Phase 1/2a clinical trial has been initiated in the first quarter of 2026. GLIX1 is being developed under a collaboration with Hemispherian AS.

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 solid tumors, including metastatic pancreatic cancer (PDAC), and has a Phase 2b PDAC trial currently ongoing under a collaboration with Columbia University.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on [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 expectations with regard to the planned Phase 1/2a GLIX1 clinical trial, expected timing of a clinical readout, and BioLineRx's business strategy. 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 GLIX1 and motixafortide 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 GLIX1 and motixafortide into clinical trials or to successfully complete its preclinical studies or clinical trials; whether the clinical trial results for GLIX1 and motixafortide will be predictive of real-world results; BioLineRx's receipt of regulatory approvals for GLIX1 and motixafortide and the timing of other regulatory filings and approvals; whether access to GLIX1 and motixafortide is achieved in a commercially viable manner and whether GLIX1 and motixafortide 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 that 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 need 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; 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 23, 2026. 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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