BioLineRx and Hemispherian Present Phase 1/2a Clinical Study and Pre-Clinical Updates, Including Brain PK/PD Data, at SNO 2026

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- Fourth cohort initiated in ongoing Phase 1/2a study of GLIX1; remaining cohorts to include patients in window-of-opportunity setting -

- GLIX1 demonstrated robust, dose-dependent antitumor activity in multiple GBM models, including confirmed evidence of brain penetration and dose-dependent increases in tumor 5hmC -

TEL AVIV, Israel and OSLO, Norway, Nov. 16, 2026 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, and Hemispherian AS, a clinical-stage oncology company developing novel small molecule therapeutics, today announced that two posters featuring GLIX1 were presented at the 31st Society for Neuro-Oncology (SNO) Annual Meeting.

"The data presented at this year's SNO Annual Meeting further strengthen our belief in GLIX1 as a treatment for GBM. In parallel, our Phase 1/2a study is progressing very rapidly with no identified safety concerns, and we continue to look forward to results from the study in the first half of next year," said Philip Serlin, Chief Executive Officer of BioLineRx. "We are particularly excited about the new window of opportunity cohorts being introduced into the study. Together with our new PK/PD data from the pre-clinical model, the data from these patients are expected to provide valuable information regarding exposure and activity in brain tumors."

"The consistency and magnitude of GLIX1's antitumor activity across multiple GBM models are highly encouraging and further support the therapeutic rationale for its novel TET2-activating mechanism," said Adam Robertson, Ph.D., Chief Scientific Officer of Hemispherian AS. "Particularly notable is the activity observed in the TMZ-resistant patient-derived model, as well as evidence of brain penetration and dose-dependent increases in tumor 5hmC, a marker of TET2 activity, in the orthotopic model, which strengthen the scientific rationale for advancing GLIX1 in glioblastoma."

Presentation Summaries:

Title: Phase 1/2a study of GLIX1, a novel first-in-class oral TET2 activator, for the treatment of recurrent or progressive high-grade glioma (CTNI-25)

Summary: This poster describes the design of the ongoing Phase 1/2a clinical study (NCT07464925) and highlights the mechanistic and pre-clinical data supporting the rationale for GLIX1 in GBM.

GLIX1-C101 is an open-label, multicenter, first-in-human study consisting of a dose-escalation phase followed by a dose-expansion phase. The study is designed to determine the recommended dose of GLIX1 as monotherapy based on assessments of safety, tolerability, disease characteristics, pharmacokinetics, pharmacodynamics and preliminary clinical activity in patients with high-grade diffuse glioma whose disease has progressed during or recurred following prior standard-of-care or investigational therapies.

The dose escalation part of the study will be followed by a dose expansion part, with doses and populations to be determined based on the first part of the study. Long-term survival follow-up is also included in the study.

The study is ongoing, with dosing initiated in the fourth cohort. No significant treatment-emergent adverse events have been observed.

Notably, remaining cohorts will include patients in a window-of-opportunity setting, providing an opportunity to directly assess GLIX1 brain penetration and biological activity in human tumor tissue, helping inform further clinical development.

Title: GLIX1, a TET2 activator targeting DNA damage response: potent anti-tumor activity across multiple glioblastoma models; orthotopic CDX models and a subcutaneous TMZ-resistant PDX model (EXTH-31)

Summary: This poster highlights the antitumor activity of GLIX1, a first-in-class, oral, brain-penetrant TET2 activator, across three orthotopic glioblastoma cell-derived xenograft (CDX) studies and a subcutaneous, temozolomide (TMZ)-resistant patient-derived xenograft (PDX) model.

In the SNB19 CDX model, GLIX1 demonstrated tumor eradication and prolonged survival. In the U87MG CDX model, GLIX1 produced dose-dependent tumor growth inhibition. In the TMZ-resistant BN2276 PDX model, GLIX1 also demonstrated tumor growth inhibition, compared to control, while TMZ was not effective.

Supporting these efficacy findings, additional pharmacokinetic and pharmacodynamic analyses in the orthotopic U87MG model demonstrated that GLIX1 was detected in the brain at all tested dose levels following oral administration, with total exposure increasing at higher doses. GLIX1 also produced dose-dependent increases in tumor genomic 5-hydroxymethylcytosine (5hmC), a marker of TET2 activity, which correlated with tumor growth inhibition.

Collectively, these preclinical findings demonstrate potent antitumor activity across multiple GBM models, including TMZ-resistant disease, supported by evidence of brain penetration and pharmacodynamic activity consistent with TET2 activation.

About the Society for Neuro-Oncology (SNO)

The Society for Neuro-Oncology (SNO) Annual Meeting brings together researchers and clinicians to share advances in brain tumor research and treatment. For more information, please visit: https://www.soc-neuro-onc.org/meetings-education/31st-society-for-neuro-oncology-annual-meeting-education-day

About Hemispherian

Hemispherian AS is a clinical-stage pharmaceutical company developing first-in-class small-molecule cancer therapies. Its lead program, GLIX1, is being advanced in partnership with BioLineRx for the treatment of glioblastoma and a broad range of solid tumors.

The company is headquartered in Oslo, Norway, and collaborates with leading academic and clinical institutions worldwide.

Learn more at www.hemispherian.com or on LinkedIn.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a clinical-stage 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 ongoing Phase 1/2a clinical trial of GLIX1; the anticipated timing and content of data from the trial; the planned inclusion of patients in window-of-opportunity cohorts; the potential for those cohorts to provide information regarding GLIX1 exposure and biological activity in human brain tumor tissue; the interpretation and potential significance of preclinical pharmacokinetic, pharmacodynamic and efficacy data; and BioLineRx's development plans and 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's 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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