BioLineRx Ltd. and Hemispherian AS Establish Joint Venture to Develop GLIX1, a First-in-Class, Oral, Small Molecule Targeting DNA Damage Response in Glioblastoma and Other Cancers

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- GLIX1 restores TET2 activity in cancer, resulting in double stranded DNA breaks in cancer cells only -

- FDA IND clearance received for Phase 1/2a study, expected to initiate in Q1 2026 -

- Glioblastoma market opportunity estimated to be in excess of $3.8 billion annually across the US and EU5 by 2030 -

- BioLineRx affirms its cash runway into the first half of 2027 -

- Management to host conference call today, September 29th, at 8:30 am EDT -

TEL AVIV, Israel and OSLO, Norway, Sept. 29, 2025 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical development stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, and Hemispherian AS, a Norwegian biotech company focused on small molecule cancer therapeutics, today announced the establishment of a joint venture (JV) to develop GLIX1, a first-in-class, oral, small molecule targeting DNA damage response in glioblastoma (GBM) and other cancers. GLIX1 agonizes TET2 activity in cancer cells, resulting in the formation of double-stranded DNA breaks and apoptosis specifically in cancer cells.

GLIX1, Hemispherian's lead drug candidate, is being developed as a potential treatment for newly diagnosed and recurrent GBM. GLIX1 has demonstrated potent anti-tumor activity in multiple glioblastoma models, excellent blood-brain barrier penetration and a favorable safety profile in preclinical toxicology studies. An Investigational New Drug (IND) application was cleared by the U.S. Food and Drug Administration (FDA) in August 2025, and a Phase 1/2a study is expected to initiate in Q1 2026. GLIX1 has also been granted Orphan Drug Designation by both the FDA and the European Medicines Agency (EMA), underscoring the substantial unmet need in this indication. In addition, GLIX1 has shown anti-tumor activity in other cancer models, and early data also suggest the potential for strong synergy of GLIX1 with PARP inhibitors, particularly in homologous recombination (HR) proficient cancers. Further development in other solid tumors is being planned.

"This joint venture combines our expertise in DNA damage response research and discovery, with BioLineRx's proven track record of clinical and regulatory success," stated Zeno Albisser, Chief Executive Officer of Hemispherian. "Glioblastoma is a notoriously challenging tumor type in urgent need of new treatment options. GLIX1 is a small molecule that crosses the blood-brain-barrier, has a novel mechanism of action targeting a DNA repair mechanism in cancer cells, and has demonstrated impressive efficacy and a favorable safety profile in pre-clinical models. We are eager to initiate the Phase 1/2a study as expeditiously as possible, and are working with leading neuro-oncology centers and the BioLineRx team to bring this promising asset to patients."

"Following a comprehensive review of pipeline expansion opportunities in oncology and rare diseases, we are thrilled to have identified a highly innovative asset such as GLIX1, with the potential to become an effective and safe treatment option for cancer patients with high unmet needs. I could not be more excited to work alongside the Hemispherian team," said Philip Serlin, Chief Executive Officer of BioLineRx. "This JV brings together highly complementary capabilities in DNA repair research, alongside clinical development and regulatory expertise, to create an entity that I believe is well positioned to bring much-needed innovation to the most challenging cancer types while creating shareholder value. The JV also has a first look at other molecules in Hemispherian's pipeline, but will initially focus on GLIX1."

Terms of the Joint Venture

Pursuant to the terms of the JV agreement, Hemispherian will contribute the global rights of GLIX1 to the JV, and BioLineRx will be responsible for managing, performing and funding all JV development activities. In consideration for their respective contributions, as of the JV's inception, Hemispherian will hold 60% of the JV's share capital, and BioLineRx will hold a 40% stake, with BioLineRx's stake increasing incrementally to a potential maximum of 70% in parallel with its continued investment in the program. The parties agreed that all funding from BioLineRx would go strictly to asset development. The JV also has a first look at other molecules in Hemispherian's pipeline.

Urgent Unmet Need and Significant Commercial Opportunity in Glioblastoma

GBM is the most common and aggressive form of primary brain cancer. The current standard of care (SoC) treatment was established in 2005, with only limited further advancements since. Treatment includes surgical resection, followed by radiotherapy, and concomitant and adjuvant chemotherapy (Temozolomide), yet most patients will succumb to their disease within less than 18 months (median OS of 12-18 months).

GBM occurs at all ages, but peaks in the fifth and sixth decades of life, with an increasing incidence in light of the aging global population. New and better treatments are desperately needed aiming at improving survival, maintaining quality of life and delaying tumor progression and symptoms.

The annual incidence of GBM is expected to be approximately 18,500 patients in the U.S. and approximately 13,400 across the EU5 (France, Germany, Italy, Spain and the United Kingdom) by 2030. Total addressable markets across both the newly diagnosed and recurrent settings

are estimated to be approximately $2.5 billion in the U.S., and approximately $1.3 billion across the 5EU at that time.

Phase 1/2a Study to be Conducted by World Leading Investigators in Glioblastoma

Dr. Roger Stupp and Dr. Ditte Primdahl of the Malnati Brain Tumor Institute of the Lurie Comprehensive Cancer Center at Northwestern University will serve as principal investigators for the study.

The Phase 1 part of the trial is expected to recruit up to 30 patients with recurrent GBM. The objective of this part 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 is anticipated in H1 2027.

The Phase 2a expansion part of the trial is planned to include three population cohorts: (1) GLIX1 as monotherapy in recurrent GBM, (2) GLIX1 in combination with standard of care in newly diagnosed GBM patients (likely a "window of opportunity" study), and (3) GLIX1 in combination with PARP inhibitors in other solid tumors.

Conference Call and Webcast Information

To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. A live webcast and a replay of the call can be accessed through the event page on the Company's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast. The call replay will be available approximately two hours after completion of the live conference call. A dial-in replay of the call will be available until October 1, 2025; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About Hemispherian AS

Hemispherian AS is a pioneering biotech company developing next-generation therapeutics for aggressive cancers. The company is focused on developing a novel class of small molecule drugs targeting the TET2 enzyme.

The company's lead compound, GLIX1, has a unique mechanism of action that selectively targets DNA repair pathways in tumor cells while sparing healthy tissue. Hemispherian has received IND clearance from the FDA to start clinical development for GLIX1. Hemispherian is based in Oslo, Norway. For more information, visit www.hemispherian.com.

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 solid tumors, for which a Phase 1/2a clinical trial will 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 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 success of the joint venture with Hemispherian, expectations with regard to the therapeutic potential of GLIX1 and the addressable market, expectations regarding the timeline for initiation of a Phase 1/2a study, the expected cash runway of BioLineRx, 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 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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