BioLineRx Announces Closing of Exclusive License Agreement to Motixafortide in Asia and Concurrent Strategic Equity Investment

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- License agreement includes $15 million upfront, up to $50 million in potential development and regulatory milestones; up to ~$200 million in potential commercial milestones, and tiered double-digit royalties on sales -

- Gloria Biosciences expected to begin bridging study to support potential approval and commercialization of motixafortide in the territory in stem cell mobilization -

- Gloria Biosciences expected to initiate randomized Phase 2/3 first-line pancreatic cancer clinical trial, evaluating motixafortide in combination with PD-1 inhibitor *zimberelimab and standard of care combination chemotherapy -

TEL AVIV, Israel, Oct. 12, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced the closing of an exclusive license agreement with Guangzhou Gloria Biosciences Co., Ltd. (GloriaBio) and an associated investor for the development of motixafortide across all indications in Asia. Motixafortide is a novel, high-affinity CXCR4 inhibitor that received approval for its first indication in September 2023 by the U.S. Food and Drug Administration (FDA) for stem cell mobilization (SCM) in autologous stem cell transplantation (ASCT) in patients with multiple myeloma. Motixafortide is also being studied for other potential uses in oncologic and hematologic diseases.

The license agreement provides for a $15 million upfront payment (which was received at closing), up to $50 million in potential development and regulatory milestones in China and Japan, and up to $200 million in potential commercial milestones based on defined sales targets. BioLineRx is also eligible to receive tiered double-digit royalties on net sales.

In addition, the transaction included an equity investment of $14.6 million in BioLineRx through the purchase of newly issued American Depositary Shares (ADSs) at a price of $2.136 per ADS in a private placement. No warrants were issued in the transaction. Along with the investment, the purchaser received the right to appoint one representative to the BioLineRx Board of Directors.

Collaboration Details

Under the terms of the license agreement, GloriaBio will be responsible for development and commercialization of motixafortide in Asia initially in SCM. With the recent FDA approval of APHEXDA for this indication, GloriaBio plans to initiate a bridging study to support potential approval and commercialization of motixafortide in the licensed territories in SCM for ASCT in patients with multiple myeloma.

In addition, GloriaBio plans to initiate a Phase 2/3 first-line pancreatic cancer clinical trial evaluating motixafortide in combination with PD-1 inhibitor *zimberelimab and standard of care combination chemotherapy. BioLineRx has been developing motixafortide in combination with PD-1 inhibitors and standard of care combination chemotherapies in pancreatic cancer, and recently announced the initiation of a randomized Phase 2 clinical trial sponsored by Columbia University in first-line metastatic pancreatic cancer based on promising preliminary data from a single-arm pilot phase reported on September 29 at the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer.

"We are tremendously pleased by the swift closing of this significant licensing agreement for the Asian market, which brings substantial benefits to BioLineRx, and ultimately, to patients, including the advancement of our two leading development programs," said **Philip Serlin**, Chief Executive Officer of BioLineRx Ltd. "Given GloriaBio's expertise and track record in the development and commercialization of cancer immunotherapies in China, we believe GloriaBio is well suited to further develop motixafortide in Asia. The combined initial investment of nearly $30 million through the upfront payment and equity investment demonstrates a clear commitment to the motixafortide programs in stem cell mobilization and pancreatic cancer in Asia, and provides us with additional capital to continue our aggressive launch plans in the U.S."

"We are very pleased to enter into this strategic partnership with BioLineRx and are committed to the development and commercialization of motixafortide in Asia, which we believe will bring additional value to GloriaBio's portfolio via clear synergies with zimberelimab," said **Jiman Zhu**, Founder of GloriaBio. "There are very significant unmet patient needs in pancreatic cancer in Asia, especially in China. We are excited to see the encouraging clinical data of motixafortide in combination with PD-1 inhibitors and chemotherapy in pancreatic cancer and look forward to initiating a Phase 2/3 randomized trial in a first-line pancreatic cancer, as well as investigating additional indications for motixafortide in Asia."

MSQ Ventures served as advisor to BioLineRx on this transaction.

About Pancreatic Cancer in Asia
At nearly 240,000 reported cases in 2022, it is estimated that Asia had the largest number of pancreatic cancer cases globally (496,000 estimated cases worldwide). In China alone, the number of pancreatic cancer cases in 2020 reached approximately 125,000, with a 5-year survival rate of just 7.2%.

About Multiple Myeloma and Autologous Stem Cell Transplantation in Asia
Multiple myeloma is an incurable blood cancer that affects some white blood cells called plasma cells, which are found in the bone marrow. When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow.
In 2022, it is estimated that Asia had over 51,000 reported cases of multiple myeloma (MM), the largest number of MM cases globally. New cases of MM reached over 20,000 in Greater China in 2018, and MM incidence is predicted to increase at an annual growth rate of 2.9%.

Autologous stem cell transplantation (ASCT) can be an important treatment paradigm for a number of blood cancers, including multiple myeloma. In China, ASCTs are included in medical insurance reimbursement, and in 2019, the total number of ASCTs in China reached more than 10,000 for the first time (for comparative purposes, as many as 14,000 ASCTs are performed each year in the U.S.).

***About Zimberelimab (YuTuo®)**
Zimberelimab is a fully human anti-PD-1 monoclonal antibody. GloriaBio is developing and commercializing zimberelimab in Greater China, including mainland China, Hong Kong, Macao and Taiwan, where zimberelimab is approved for relapsed or refractory classical Hodgkin's lymphoma and

recurrent or metastatic cervical cancer. Arcus Biosciences, and development partner Gilead Sciences, have the exclusive rights to develop and commercialize zimberelimab throughout the world except in Greater China and certain territories.

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 theU.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.

About Gloria Biosciences
Gloria Biosciences is a commercial stage biopharma company focused on the development and commercialization of novel or highly differentiated immunotherapies and biologics for oncology. Toward the company's ultimate goal of improving accessibility, affordability, and availability for patients with innovation, Gloria Biosciences is striving to build a pipeline of more efficacious and patient-centered treatments to address unmet medical needs, driven by the company's efficient execution of clinical development, proven fast-to-market commercialization ability, world-class GMP-compliant manufacturing capability and global partnerships.

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 benefits of APHEXDA, the timing and execution of the launch of APHEXDA and the plans and objectives of management for future operations and 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 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, manage, and maintain corporate collaborations, as well as the ability of its collaborators to execute on their development and commercialization plans; 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 and the Russian invasion of Ukraine, 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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