BioLineRx Announces Completion of Enrollment of Phase 1/2a Study of Innovative Intratumoral Cancer Vaccine, AGI-134, in Unresectable Metastatic Solid Tumors

January 24, 2022

- Initial results anticipated in the first half of 2022

TEL AVIV, Israel, Jan. 24, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical Company focused on oncology, today announced that the Company has completed enrollment of the Phase 1/2a study of its innovative intratumoral cancer vaccine candidate, AGI-134, designed to evaluate the safety and biological activity of AGI-134 in patients with unresectable metastatic solid tumors. Results of AGI-134's safety and proof of mechanism are anticipated in the first half of 2022.

"The completion of enrollment of the AGI-134 first-in-man study is a very significant milestone for our Company, especially taking into account the difficulties caused by the COVID-19 pandemic on patient recruitment," stated Philip Serlin, Chief Executive Officer of BioLineRx. "AGI-134, our second clinical-stage oncology asset, has a unique mode of action, applicable to all injectable tumor types. In preclinical models, AGI-134 led to regression of primary tumors, prevented growth of secondary tumors via an abscopal effect, and triggered a vaccine effect that we believe may prevent the development of metastases. This clinical study aims to confirm the proposed mechanism of action and safety profile of AGI-134 in humans, based on which we also plan to explore potential combinations as part of its future clinical development program."

The Phase 1/2a study is a multicenter, open-label study, which recruited a total of 38 patients in the UK, Spain and Israel, and is comprised of two parts. Part 1 was completed, and was an accelerated dose-escalation study in five patients, to determine the maximum tolerated dose and the recommended dose for part 2 of the study. Part 2 is a dose expansion study at the recommended dose in 33 patients, designed to evaluate the safety and tolerability of AGI-134, and to validate AGI-134's mechanism of action using a wide array of biomarkers. For more information on this Phase 1/2a study, see NCT03593226.

On December 15, BioLineRx announced the formation of an Immuno-Oncology Scientific Advisory Board (SAB) to provide insight and guidance on the Company's immuno-oncology activities. The SAB, which has provided valuable guidance to the AGI-134 development program, is comprised of recognized key opinion leaders in the fields of cancer immunology, intra-tumoral cancer treatments and clinical development.

About AGI-134

AGI-134 is a synthetic alpha-Gal glycolipid in development for solid tumors that is highly differentiated from other cancer immunotherapies. AGI-134 is designed to label cancer cells with alpha-Gal via intra-tumoral administration, thereby targeting the body's pre-existing, highly abundant anti-alpha-Gal (anti-Gal) antibodies and redirecting them to treated tumors. Binding of anti-Gal antibodies to the treated tumors results in activation of the complement cascade, which destroys the tumor cells and creates a pro-inflammatory tumor microenvironment that also induces a systemic, specific anti-tumor (vaccine) response to the patient's own tumor neo-antigens.

AGI-134 has been evaluated in numerous pre-clinical studies. In a mouse melanoma model, treatment with AGI-134 led to regression of established primary tumors and suppression of secondary tumor (metastases) development. Synergy has also been demonstrated in additional pre-clinical studies when combined with an anti-PD-1 immune checkpoint inhibitor, offering the potential to broaden the utility of such immunotherapies, and improve the rate and duration of responses in multiple cancer types. AGI-134 was obtained by BioLineRx through the acquisition of Agalimmune Ltd.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study, has successfully completed a pre-NDA meeting with the FDA, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

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 "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties 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; 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; BioLineRx's ability to establish and maintain corporate collaborations; 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 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; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 February 23, 2021. 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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