BioLineRx Successfully Completes Dose-Escalation Part of Phase 1/2a Clinical Study for AGI-134, a Novel Immunotherapy for Treatment of Solid Tumors

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AGI-134 was found to be safe and well tolerated with no dose-limiting toxicities observed
Dose expansion part of study expected to commence shortly, with initial results expected by year-end 2020

TEL AVIV, Israel, Sept. 3, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today that it has successfully completed the dose-escalation part of the Phase 1/2a clinical study for AGI-134, a novel compound that evokes a direct anti-tumor response, as well as a vaccine effect, via a unique, multi-arm mechanism that targets patient-specific tumor neoantigens. AGI-134 was found to be safe and well tolerated, with no serious drug-related adverse events or dose-limiting toxicities reported. The maximal tolerated dose was not reached and the recommended dose for part 2 of the study was determined.

The ongoing Phase 1/2a study is a multicenter, open-label study expected to take place at approximately 15 sites in the US, UK and Israel. The objectives of the study are to evaluate the safety and tolerability of AGI-134 at the recommended dose in multiple solid tumor types, to evaluate a wide array of biomarkers, and to validate AGI-134's mechanism of action. Furthermore, efficacy will be assessed by clinical and pharmacodynamic parameters. The dose-expansion part 2 of the study is expected to commence shortly.

Prof. Mark Middleton of the University of Oxford, the study's principal investigator, stated, "We are pleased with these initial safety results of the first-in-human clinical trial assessing AGI-134 for the treatment of solid tumors. AGI-134 represents a new mechanistic class of cancer immunotherapies, with a unique and highly differentiated mode of action, harnessing pre-existing immune machinery to trigger a systemic anti-tumor response and create a pro-inflammatory tumor microenvironment. We expect the mechanistic assessments performed during the study to further elucidate and confirm AGI-134's activity. These assessments are ongoing and will be extended during part 2 of the study."

"We are excited with the positive results of the first part of the Phase 1/2a of our second lead oncology asset," said Philip Serlin, Chief Executive Officer of BioLineRx. "Numerous pre-clinical studies to date have demonstrated that treatment with AGI-134 leads to regression of established primary tumors, prevents growth of untreated distal secondary tumors, and triggers a vaccine effect that may prevent the development of future metastases. Following the FDA's recent IND approval for AGI-134, we plan to add sites in the US to the study, which is currently being conducted in the UK and Israel, by the first half of 2020. We are looking forward to initiating part 2 of the study shortly, with initial results expected by year-end 2020."

"In addition, we are also waiting with great anticipation for the upcoming top-line data for BL-8040's COMBAT/KEYNOTE-202 trial in pancreatic cancer, which is running according to schedule and is expected to read out by the end of the year," added Mr. Serlin.

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 is a clinical-stage biopharmaceutical company focused on oncology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is being investigated in a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in two Phase 1b/2 studies for solid tumor indications.

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. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

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. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. 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 28, 2019. 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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