BioLineRx Announces FDA Approval of IND Application for AGI-134, a Novel Immunotherapy Anti-Cancer Vaccine for Solid Tumors

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- Phase 1/2a study ongoing in the UK and Israel, with sites in the US expected to join by H1 2020 -

- Initial safety results expected in H2 2019; initial efficacy results expected by year-end 2020 -

TEL AVIV, Israel, May 7, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for AGI-134, a novel immunotherapy anti-cancer vaccine for solid tumors.

"We are pleased with the FDA's IND approval, which will enable us to expand our ongoing Phase 1/2a study, currently being carried out in the UK and Israel, to the US by the first half of 2020," said Philip Serlin, Chief Executive Officer of BioLineRx. "Pre-clinical studies have demonstrated that treatment with AGI-134 leads to complete regression of primary tumors, prevents growth of untreated distal secondary tumors, and triggers a vaccine effect that may prevent the development of future metastases. Furthermore, preclinical studies have also shown that, in addition to the monotherapy effect, the combination of AGI-134 with an anti-PD-1 immune checkpoint inhibitor demonstrates a synergistic effect in protection from secondary tumor growth. We look forward to the initial safety results of the trial in the second half of this year and anticipate initial efficacy results by the end of 2020."

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 study is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in solid tumors. Additional objectives include a wide array of biomarker endpoints, as well as validation of AGI-134's mechanism of action. Furthermore, efficacy will be assessed by clinical and pharmacodynamic parameters.

The study is comprised of two parts: (i) the ongoing accelerated dose-escalation part to assess the safety and tolerability of intratumorally injected AGI-134 as a monotherapy, as well as to determine the maximum tolerated dose and the recommended dose for part 2 of the study; and (ii) a dose expansion part at the recommended dose, comprised of three cohorts and designed to assess the safety, tolerability and anti-tumor activity of AGI-134 as a monotherapy in a basket cohort of multiple solid tumor types, as well as in two additional cohorts in combination with an immune checkpoint inhibitor – in metastatic colorectal cancer and in head and neck squamous cell carcinoma.

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 intratumoral 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 several Phase 1b/2 studies for multiple solid tumor indications and AML.

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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