



BioLineRx Announces Receipt of FDA Biological Product Designation for Novel Cancer Immunotherapy Candidate AGI-134

November 20, 2018

**- Designation provides eligibility for 12 years of market exclusivity that complements robust IP estate -
- Phase 1/2a study ongoing with topline data expected by year-end 2020 -**

TEL AVIV, Israel, Nov. 20, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that the U.S. Food and Drug Administration (FDA) has granted the Biological Product Designation for AGI-134, the Company's novel immunotherapy compound. This designation provides the Company with eligibility to obtain 12 years of market exclusivity upon approval of the product for commercial use by the FDA. This regulatory market exclusivity adds an incremental layer of protection in addition to that afforded by existing patents granted in the United States and Europe, and pending in other countries, covering the use of AGI-134 for the treatment of solid cancer tumors. These patents are valid until May 2035, with a possible term extension of up to five additional years.

"We are extremely pleased to receive the FDA's Biological Product Designation for AGI-134, our second lead oncology asset. This classification as a biological product is very significant, since it provides us with additional valuable exclusivity and confirms the FDA's acceptance of AGI-134's main mechanism of action as a vaccine," 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, in prior studies, the combination of AGI-134 with an anti-PD-1 immune checkpoint inhibitor demonstrated a synergistic effect in protection from secondary tumor growth. We recently initiated a Phase 1/2a study of this promising product in solid tumors, as both monotherapy and in combination with checkpoint inhibitors, and we anticipate initial top-line results from this important study by the end of 2020."

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 and immunology. 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 has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated 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 (known as Merck in the US and Canada), on the basis of which the Company is carrying out a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; 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 6, 2018. 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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