



## BioLineRx Reports Data at ASCO-SITC Conference Showing Complete Tumor Regression by AGI-134 in Pre-Clinical Studies

January 23, 2018

**- AGI-134 on track to commence Phase 1/2a clinical study in H1 2018 -**

TEL AVIV, Israel, January 23, 2018 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX) (TASE: BLRX.TA), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that AGI-134, an immunotherapy compound in development for the treatment of multiple solid tumors, demonstrated successful results in two pre-clinical melanoma studies. Results of these studies will be presented as a poster titled "[Intratumoral Administration of the Alpha-Gal Glycolipid AGI-134 to Induce Tumor Regression in a Mouse Model of Melanoma](#)" (Abstract 68) on January 25, 2018 at the ASCO-SITC Clinical Immuno-Oncology Symposium, being held January 25-27, 2018, in San Francisco, CA.

The ability of intratumorally injected AGI-134 to induce regression of established primary tumors was assessed in two murine melanoma models. In the two models, there was complete tumor regression in 50% and 67%, respectively, of mice treated with AGI-134. Moreover, treatment with AGI-134 showed a beneficial effect on survival, compared to the control group. In addition, the results show that injection of AGI-134 into the tumors induces activation of the complement system, an important component of the innate immune system. Activation of the complement system within tumors by AGI-134 is predicted to destroy tumor cells and create a pro-inflammatory tumor microenvironment that attracts and activates other immune cells, ultimately resulting in adaptive anti-tumor immunity. Previous studies with intratumoral administration of AGI-134 to primary tumors had shown that AGI-134 protects mice from the development of distant, untreated tumors.

"We are pleased to report these encouraging results for our second lead oncology project at the upcoming ASCO-SITC conference," said Philip Serlin, Chief Executive Officer of BioLineRx. "Previous studies have demonstrated that intratumoral administration of AGI-134 induces a systemic anti-tumor response that protects mice from the development of distant tumors. These new studies now show direct regression of established primary tumors after injection with AGI-134, and that this regression is associated with activation of the innate immune system. These compelling pre-clinical data support investigating this approach in a Phase 1/2a study, and we are excited and on track to commence a first-in-man study with this promising novel oncology asset in patients with solid tumors in the first half of 2018."

### About AGI-134

AGI-134 is a synthetic alpha-Gal immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant anti-alpha-Gal antibodies to induce a systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. AGI-134 has completed numerous pre-clinical studies, demonstrating robust protection against the development of secondary tumors in a model of melanoma with a single dose only. Synergy has also been demonstrated in additional pre-clinical studies when combined with a 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 is expected to initiate a first-in-man study in the first half of 2018. 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 (tradename of Merck & Co., Inc.), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and MSD'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 <http://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 23, 2017. 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.*

### Contacts:

PCG Advisory  
Vivian Cervantes  
Investor Relations  
+1-646-863-6274  
[vivian@pcgadvisory.com](mailto:vivian@pcgadvisory.com)

Tsipi Haitovsky  
Public Relations  
+972-52-989892  
[tsipihai5@gmail.com](mailto:tsipihai5@gmail.com)

SOURCE BioLineRx Ltd.