



## **BioLineRx Announces Acquisition of Agalimmune Ltd. to Accelerate Expansion of Immuno-Oncology Pipeline**

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### **Agalimmune's Lead Asset, AGI-134, Provides a Unique Approach for Eliciting Patient-specific, Anti-tumor Immune Responses in Multiple Cancer Types**

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BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that it has acquired Agalimmune Ltd., a private UK-based company with an innovative, anti-cancer immunotherapy platform. Acquisition consideration consisted of a \$6 million upfront payment, of which \$3 million is in cash and the remainder in BioLineRx shares. Additional future payments may be made based on development and commercial milestones.

Agalimmune's lead compound is AGI-134, 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 is in near-clinical development and is expected to commence a first-in-man study in patients with solid tumors in the first half of 2018.

Philip Serlin, Chief Executive Officer of BioLineRx, stated, "Immuno-oncology is one of the most promising approaches for the treatment of cancer. Although a number of current immunotherapies are receiving widespread attention, many solid tumors are still able to evade the immune system's surveillance. Most immunotherapies work best in highly mutated tumors that are infiltrated with immune cells, known as 'hot' tumors. Unfortunately, the overwhelming majority of tumors are 'cold' tumors, and thus transforming a 'cold' tumor into a 'hot' tumor is a major objective in cancer treatment."

"In this regard, Agalimmune's lead asset, AGI-134, harnesses naturally occurring, pre-existing antibodies to elicit a tumor-specific immune response that is unique to the treated individual and provides a universal, small-molecule approach to personalized immunotherapy. The subsequent stimulation and recruitment of T cells, which recognize the patient's own neo-antigens, to the tumor site, has the potential of transforming 'cold' tumors into 'hot' ones. Through this important acquisition, we will also benefit from Agalimmune's complementary immunology expertise and facilities in the UK, which support our strategic focus in this area. We are enthusiastic to incorporate into our pipeline this promising near-clinical asset, which substantially strengthens our position in the immuno-oncology space," added Mr. Serlin.

"We are very excited that we found an ideal partner for our promising therapeutic pipeline. We are extremely impressed by BioLineRx's proven drug development capabilities, as well as their meaningful collaborations with global pharmaceutical companies," said Damian Marron, CEO of Agalimmune. "We strongly believe in the value of our unique platform and we look forward to its accelerated clinical development by BioLineRx."

#### **About Agalimmune and AGI-134**

Agalimmune Ltd. is a biopharmaceutical company with an innovative anti-cancer immunotherapy pipeline for generating a systemic, adaptive immune response to solid tumors. It was established in 2013 and is headquartered in London, England with laboratories in Sandwich, England and Boston, Massachusetts.

AGI-134, Agalimmune's lead molecule 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. Alpha-Gal is a cell-surface carbohydrate antigen which is not expressed by humans, unlike virtually all other mammals and bacteria. Therefore, humans universally produce and maintain high levels of anti-Gal antibodies, due to exposure to alpha-Gal on bacteria in the digestive system.

AGI-134 is injected into the tumor, where it coats the tumor cell membranes, resulting in alpha-Gal being exposed on the tumor cell surface. Anti-Gal antibodies bind to the alpha-Gal part of AGI-134 to produce an initial immune response that activates complement-dependent and antibody-dependent cellular cytotoxicity (cell death). This cytotoxicity generates immune-tagged cells and cellular debris that trigger an uptake of tumor-associated antigens by antigen-presenting cells (APCs). These APCs induce a follow-on systemic immune response by the activation and clonal expansion of T cells (CD8+) to the patient's own neo-antigens. This approach not only targets the primary injectable tumor, but has also demonstrated efficacy against existing distant secondary tumors. Furthermore, the mechanism of action suggests the potential of long-term protection against future metastases. The use of intratumoral alpha-Gal glycolipids to treat solid tumors was invented by Prof. Uri Galili, Ph.D., while at the University of Massachusetts, from where the intellectual property rights were licensed. The intellectual property rights relating to AGI-134 were in-licensed from KODE Biotech Ltd., the inventors of AGI-134.

#### **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 and is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 2 study in stem cell mobilization for allogeneic 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 (known as Merck in the US and Canada), on the basis of which the Company has initiated 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 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 10, 2016. 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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