



## BioLineRx Announces Results from Phase 1/2 Study for Celiac Treatment

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*BL-7010 well tolerated in both single- and repeated-dose administrations*

*Supports classification as medical device in Europe due to lack of systemic absorption*

*Company to investigate lower doses of BL-7010 prior to commencing efficacy study expected in early 2015*

JERUSALEM--(BUSINESS WIRE)--Jul. 16, 2014-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today unblinded results from its Phase 1/2 study for BL-7010, a novel polymer for the treatment of celiac disease.

The Phase 1/2 study, taking place at Tampere Hospital in Finland, a world-leading site for celiac disease research, is a two-part (single and repeated administration), double-blind, placebo-controlled, dose escalation study of BL-7010 in up to 32 well-controlled celiac patients. The primary objective of the study is to assess the safety of single and repeated ascending doses of BL-7010. Secondary objectives include an assessment of the systemic exposure, if any, of BL-7010.

During the single-administration part of the study, six dose levels of BL-7010 were evaluated compared to placebo in a 6+2 standard design, with six patients on BL-7010 and two patients on placebo. This escalation stage reached the highest planned dose with no serious or dose-limiting adverse events. All planned doses were safe and well-tolerated with all patients completing this part of the study. During the second, repeated-administration part of the study, each patient received either 3 grams of BL-7010 or placebo for 14 days, three times per day, in the same 6+2 standard design.

BL-7010 was well-tolerated over 14 days of treatment, with only one patient not completing the 14-day treatment period. Gastrointestinal-related adverse events (primarily diarrhea) were reported in six out of eight patients, though none were considered serious or dose-limiting and were also observed in one of the two patients on placebo. In light of these findings, and based on pre-clinical studies where the efficacious dose is predicted to be lower than the dose tested in the repeated administration stage of the study, the Company intends to further investigate lower repeated doses of BL-7010 in order to select the optimal dose for the upcoming efficacy study, which is expected to commence in early 2015.

Importantly, pharmacokinetic analyses revealed no systemic exposure of BL-7010 in plasma and urine samples from all patients at all doses and time points tested, both in the single- and repeated-dose regimens. Based on previous communications with a Notified Body in the European Union, the lack of systemic exposure will likely support a medical-device classification in Europe for BL-7010.

Dr. Kinneret Savitsky, CEO of BioLineRx, said, "We are pleased with these unblinded results. In particular, we are very encouraged that the results support previous pre-clinical results showing that BL-7010 is excreted in the feces and is not absorbed systemically. This will most likely support a medical device classification for this promising product in Europe, which can significantly accelerate and reduce the cost of development. Though not serious or dose-limiting, our decision to expand the dosing range in order to potentially mitigate the gastrointestinal events observed in the study is based on preclinical evidence suggesting efficacy at lower repeat doses. In the next few months we will concentrate on selecting the optimal dose of BL-7010, and, following this selection, we plan to commence in Europe a randomized, placebo-controlled efficacy study in celiac patients early next year."

### **About BL-7010**

BL-7010 is a novel, non-absorbable, orally available polymer intended for the treatment of celiac disease. It has a high affinity for gliadins, the immunogenic proteins present in gluten that cause celiac disease. By sequestering gliadins, BL-7010 effectively masks them from enzymatic degradation and prevents the formation of immunogenic peptides that trigger the immune system. This significantly reduces the immune response triggered by gluten. BL-7010 is excreted with gliadin from the digestive tract and is not absorbed into the blood. The safety and efficacy of BL-7010 have been demonstrated in pre-clinical and clinical studies. BL-7010 was invented by Prof. Jean-Christophe Leroux from the Department of Chemistry and Applied Biosciences, Institute of Pharmaceutical Sciences, ETH Zurich, Switzerland, and is being developed by BioLineRx under a worldwide exclusive license agreement with Univalor.

### **About Celiac Disease**

Celiac disease is a chronic, autoimmune, inflammatory disease of the small intestine characterized by damage to the lining of the small intestine and typically leads to dyspepsia, malabsorption and a variety of other symptoms. It occurs in genetically predisposed individuals and is caused by an immunological reaction to gluten, found in wheat, barley and rye. Estimates suggest that 1% of the world's population is affected by celiac disease, and prevalence is expected to increase dramatically with improved diagnosis and awareness of the disease. The celiac market is projected to reach \$8 billion by 2019. There are currently no treatments approved for celiac disease and the only treatment option is a life-long, strict, gluten-free diet, which is difficult to maintain both due to food contamination with gluten, as well as eating habits in a social setting.

### **About BioLineRx**

BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which is in the midst of a Phase 1/2 study.

For more information on BioLineRx, please visit [www.bioplinerx.com](http://www.bioplinerx.com) or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

*Various statements in this release concerning BioLineRx's future expectations, including specifically those related to the development and commercialization of BL-7010, 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 17, 2014. 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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