



## BioLineRx Announces Successful Final Results of Phase 1/2 Study for Novel Celiac Treatment

November 5, 2014

**- Optimal safe dose of BL-7010 determined for upcoming randomized efficacy study -**

**- Lack of systemic exposure of BL-7010 likely supports medical-device classification in Europe -**

JERUSALEM--(BUSINESS WIRE)--Nov. 5, 2014-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today successful final results from its Phase 1/2 study for BL-7010, a novel co-polymer for the treatment of celiac disease. BL-7010 was found to be safe and well tolerated in both single- and repeated-dose administrations, and the optimal safe dose for future development was determined. Over the next few months, the Company will conduct additional non-clinical studies and formulation development for BL-7010 in preparation for the upcoming randomized, placebo-controlled efficacy study, which BioLineRx expects to commence in the second half of 2015.

In all single- and repeated-administration cohorts, pharmacokinetic analyses revealed no systemic exposure of BL-7010 in plasma and urine samples. Based on previous communications with a Notified Body in the European Union, the lack of systemic exposure will likely support a medical-device classification for BL-7010, which would significantly accelerate its development in Europe.

Based on its strong safety and tolerability profile, BioLineRx has selected the one gram, three times per day regimen of BL-7010 as the optimal repeated dose for the upcoming efficacy study. Decreasing the dose to these levels substantially reduced the gastrointestinal (GI)-related adverse events (primarily diarrhea) observed previously at higher doses, while remaining within the anticipated therapeutic window for BL-7010 based on non-clinical studies.

Dr. Kinneret Savitsky, CEO of BioLineRx, said, "BL-7010 for the treatment of celiac disease is one of our lead clinical programs, and we are very pleased with the positive final results of this Phase 1/2 safety study of BL-7010, and the determination of the optimal safe dose for continued development. We are also very encouraged that the results further support previous non-clinical data showing that BL-7010 is not absorbed systemically. This will most likely support an expedited development pathway for the product in Europe."

"Celiac disease is highly prevalent throughout the world, with over 1% of the global population suffering from this disease. Nevertheless, there are currently no approved celiac therapies aside from a strict and lifelong gluten-free diet, which is exceptionally difficult and costly to maintain. Despite the significant need for new treatments, there are only a handful of clinical-stage projects under development worldwide for this disease, which we view as a significant opportunity for our product," concluded Dr. Savitsky.

### **About BL-7010's Phase 1/2 Study**

The Phase 1/2 study was a two-part (single and repeated administration), double-blind, placebo-controlled, dose-ranging study of BL-7010 in well-controlled celiac patients. The primary objective of the study was to assess the safety of single and repeated ascending doses of BL-7010. Secondary objectives include an assessment of the compound's systemic exposure, if any. During the single-administration part of the study, several dose levels of BL-7010 were evaluated compared to placebo in a 6+2 standard design, with six patients receiving BL-7010 and two patients receiving placebo at each dose level. During the repeated-administration part of the study, several doses of either BL-7010 or placebo were tested for 14 days (three times per day) in the same 6+2 standard design. A total of 32 patients participated in the study, most of whom received more than one dose level of BL-7010 or placebo.

### **About BL-7010**

BL-7010 is a novel, non-absorbable, orally available co-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, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which has completed a Phase 1/2 study.

For more information on BioLineRx, please visit [www.biolineRx.com](http://www.biolineRx.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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