



## BioLineRx Receives Regulatory Approval to Commence Phase 1/2 Trial for Novel Treatment of Celiac Disease

November 4, 2013

**- Study expected to begin by end of 2013 -  
- Results expected in mid-2014 -**

JERUSALEM, Nov. 4, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that it has received regulatory approval from the Finnish National Supervisory Authority for Welfare and Health (Valvira) to commence a Phase 1/2 safety trial for BL-7010, for the treatment of celiac disease. The study is expected to begin by the end of this year.

(Logo: <http://photos.prnewswire.com/prnh/20130730/630769>)

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

Professor Markku Maki, M.D., Ph.D., of the University of Tampere School of Medicine and the Tampere Center for Child Health Research in Finland, the responsible coordinating investigator of the trial, stated, "Celiac has become an increasingly problematic condition, with 1% of the world's current population suffering from this disease. The incidence of celiac is also expected to increase substantially in the future, with increased awareness and improved diagnostic tools. Despite the unmet medical need, the only current treatment is life-long adherence to a gluten-free diet, which is extremely difficult to maintain. Research results show that even up to 50% of patients on a gluten-free diet are still symptomatic and that small intestinal mucosal injury persists despite attempts to adhere to the diet."

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, said "BL-7010 is a significant opportunity for us, considering there are no approved treatments for celiac disease and there are very few clinical-stage projects worldwide currently being developed for this disease. We look forward to commencing the Phase 1/2 safety study for BL-7010 by the end of the year, followed by an efficacy study, which we hope to commence in the second half of 2014."

### **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. BL-7010 is excreted with gliadin from the digestive tract, preventing the absorption of gliadins' peptides into the blood. This significantly reduces the immune response triggered by gluten. The safety and efficacy of BL-7010 were demonstrated in pre-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 biopharmaceutical development company dedicated to building a portfolio of products for unmet medical needs, as well as those with advantages over currently available therapies. 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 Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in late 2013; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which is expected to commence a Phase 1/2 study in late 2013.

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 12, 2013. 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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