



BioLineRx Announces Regulatory Submission for Phase 1/2 Trial for Novel Treatment of Celiac Disease

September 24, 2013

**- Study expected to begin in Q4 2013 -
- Results expected in mid-2014 -**

JERUSALEM, Sept. 24, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that it has filed the necessary regulatory submissions to commence a Phase 1/2 trial for BL-7010 - for the treatment of celiac disease - with the Finnish National Supervisory Authority for Welfare and Health (Valvira). The relevant ethics committee has already approved commencement of the study.

(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 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. The CRO and data management vendors have already been selected for the study, which is expected to start in the fourth quarter of this year.

"We look forward to commencing the Phase 1/2 clinical study for BL-7010 by the end of the year. The study will be conducted in Finland, which has a significantly higher prevalence of celiac disease than other countries and is a world leader in celiac research," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "We are very enthusiastic about this unique product, which is generating a lot of excitement from both the scientific and medical communities. Despite the unmet medical need and the huge size of the celiac market, there is no available treatment for the disease apart from a lifelong gluten-free diet, which is extremely difficult to maintain. Since there are also very few products currently in clinical-stage development, we see a significant opportunity in this market for our product."

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 eventually 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, in 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. Today there are no pharmacological agents 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 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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