

## BioLineRx Announces Publication of Pre-clinical Results Demonstrating Efficacy of BL-7010, an Oral Treatment for Celiac Disease and Gluten Sensitivity

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**Hebrew Version** 

**Jerusalem, Israel – February 21, 2012** – BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced the publication of pre-clinical results demonstrating that BL-7010, an orally available treatment for celiac disease, reduces gluten toxicity (the negative effect of gluten on the patient's body). The research was published in the February edition of Gastroenterology.

The findings indicate that BL-7010 (previously called P(HEMA-co-SS)) reduces digestion of wheat gluten, thereby decreasing its toxicity. In addition, BL-7010 attenuates the immune response to gluten in rodents and prevents gluten-induced pathological damage to the small intestine. BL-7010 was not absorbed systemically, indicating its safety as a gluten-neutralizing substance. These data demonstrate that BL-7010 has the potential to be an effective adjunctive therapy to the gluten-free diet, to prevent or reduce gluten-induced disorders in humans.

"Celiac disease is a highly prevalent autoimmune disease, which occurs in genetically predisposed individuals who are exposed to gluten, a protein found in wheat, barley and rye," said Dr. Kinneret Savitsky, CEO of BioLineRx. "Currently, there is no cure or pharmacological treatment for the disease, and treatment consists of adhering to a life-long, strict, gluten-free diet, which is extremely hard to maintain and is not effective in all cases. BL-7010 may attenuate the immune response to gluten and reduce subsequent damage to the small intestine. This compound, therefore, has the potential to be an effective adjunctive pharmacological therapy to improve the quality of life for millions of celiac disease patients."

BL-7010 is a novel, non-absorbable, orally available polymer intended for the treatment of celiac disease and gluten sensitivity. It has a high affinity for gliadins, the immunogenic peptides present in gluten that cause celiac disease. BL-7010 acts locally in the gastrointestinal tract, masking gliadins and then undergoing excretion. This significantly reduces the immune response triggered by gluten.

## **About Celiac Disease and Gluten Sensitivity**

Celiac Disease (CD) 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 population is affected by celiac disease although prevalence is expected to increase dramatically with improved diagnosis and awareness of the disease. Today there are no pharmacological agents approved for CD 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. Non-celiac gluten sensitivity is a common name for cases of gluten reactions in which neither allergic nor autoimmune mechanisms are involved or can be identified.

## About BioLineRx

BioLineRx Ltd. is a publicly-traded biopharmaceutical development company. It is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of five clinical stage candidates: BL-1020 for schizophrenia has commenced a Phase II/III study; BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, is currently undergoing a pivotal CE-Mark registration trial and has been out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I development and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed Phase I. In addition, BioLineRx has 13 products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase III) and commercialization.

For more information on BioLineRx, please visit www.biolinerx.com.

Various statements in this release concerning BioLineRx's future expectations, plans and prospects, including, without limitation, statements relating to the ability to develop and commercialize the BL-7010 project, 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 Form 20-F filed with the Securities and Exchange Commission on July 15, 2011. 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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