



For immediate release

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

- The new safety data, as well as pre-clinical efficacy results, presented at the Better Life for Coeliacs 2012 Conference –

Jerusalem, Israel – September 10, 2012 – BioLineRx (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, announced today that BL-7010, an orally available treatment for celiac disease, was found to be safe and well tolerated in pre-clinical studies conducted to date. The new findings were delivered in an oral presentation by Professor Elena Verdú, Division of Gastroenterology, Department of Medicine, McMaster University, Hamilton, Ontario, at the [Better Life for Coeliacs 2012 Conference](#), held in Helsinki, Finland from September 6th-9th. In her talk, Prof. Verdú also presented previously disclosed pre-clinical data demonstrating that BL-7010 reduces gluten toxicity, which were published in the leading medical journal [Gastroenterology](#).

In pre-clinical studies BL-7010 was found to be safe, well tolerated and did not cause any clinical adverse effects, even in very high doses. Additional studies showed that BL-7010 is specific to gliadins, the immunogenic peptides present in gluten that cause celiac disease, and does not interact with non-related enzymes or vitamins in the digestive tract. These results imply that BL-7010 will not affect the absorbance of vitamins or the digestion process and therefore will not lead to malnutrition.

"These new findings for BL-7010, in addition to the pre-clinical efficacy data are very encouraging, especially since BL-7010 was found to be safe and without adverse effects in laboratory animals even in doses much higher than the expected clinically effective dose. Currently, the only effective treatment for celiac is a gluten free diet, which is extremely difficult to maintain, and significantly affects the quality of life of people with celiac disease. Therefore, there is a critical need for developing a safe and effective drug that could help, alongside the dietary restrictions, in preventing damage caused to the digestive tract by gluten," **said Professor Elena Verdú, who presented the data.** "BL-7010 may attenuate the immune response to gluten and reduce subsequent damage to the small intestine, and may therefore be an effective adjuvant therapy that will improve the quality of life for people with celiac disease throughout the world."

Additional efficacy studies indicate that BL-7010 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 is 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.

About BL-7010

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. By binding to gliadins, BL-7010 effectively masks them from the immune system in the digestive tract, and the BL-7010-gliadin complex is eventually excreted from the digestive tract. 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 world's population is affected by celiac disease, and 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 is a publicly-traded biopharmaceutical development company. BioLineRx 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 six clinical stage candidates: BL-1020 for schizophrenia is currently undergoing a Phase II/III study; BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; 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, BL-7040 for treating inflammatory bowel disease (IBD) has commenced a Phase II trial, and BL-8040 for treating acute myeloid leukemia (AML) has completed Phase I. In addition, BioLineRx has nine products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, 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, 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 22, 2012. 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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