



BioLineRx Enters Clinic with Novel Treatment for Celiac Disease

December 18, 2013 12:01 PM IST

- Results of Phase 1/2 trial for BL-7010 expected in mid-2014 -

JERUSALEM, Dec. 18, 2013 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today enrollment of the first patient in a Phase 1/2 trial of BL-7010, for the treatment of celiac disease. The first patient was enrolled at Tampere Hospital in Finland, a world-leading site for celiac disease research. Results are expected in mid-2014.

(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. 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 systemic exposure, if any, of BL-7010 in the study patients.

"The commencement of BL-7010's Phase 1/2 study in a world-leading celiac treatment center is an important milestone in the development of one of our most promising projects," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "Based on our pre-clinical results to date, we are very enthusiastic about this unique product, which is also generating a lot of excitement from both the scientific and medical communities. Celiac disease is an autoimmune condition that causes damage to the small intestine, and is associated with other autoimmune disorders, as well as with osteoporosis, infertility, neurological conditions and even cancer. Although 1% of the world's population suffers from this disease, there are currently no approved celiac therapeutics, and the only treatment available today is a gluten-free diet that is exceptionally difficult and costly to maintain. In addition, there are an extremely small number of clinical-stage projects under development worldwide for celiac disease, which we see as a significant opportunity for our product."

Dr. Savitsky concluded, "We anticipate 2014 to be a significant year for BioLineRx marked by several important milestones across our clinical-stage development programs, among which we are now pleased to include BL-7010. We are looking forward to the results of this Phase 1/2 safety study, expected in mid-2014, to be followed by an efficacy study that 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 gliadin 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, 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 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 early 2014; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which recently commenced a Phase 1/2 study.

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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