BIOLINERX

BioLineRx to Present Successful Results of Phase 1/2 Study for Novel Celiac Treatment at International Celiac Disease Symposium

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TEL AVIV, Israel--(BUSINESS WIRE)--Jun. 17, 2015-- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that it will present positive safety results of its Phase 1/2 study for BL-7010, a novel polymer for the treatment of celiac disease, at the 16th International Celiac Disease Symposium (ICDS 2015), to take place from June 21-24 in Prague, Czech Republic. The Phase 1/2 results were previously announced in November 2014.

Yotam Nisemblat, BioLineRx Drug Development Director, will present the data in a talk titled <u>BL-7010, a Novel Potential Treatment of Celiac Disease</u> - <u>a Phase 1/2 Safety Study in Celiac Patients</u>, on Wednesday, June 24, in the Novel Treatments session. BL-7010 was found to be safe and well tolerated in the single-dose phase, and the optimal safe dose for future development was determined in the repeated-dose phase. The Company is in the final stages of additional non-clinical studies and formulation development for BL-7010 in preparation for the upcoming randomized, placebo-controlled efficacy study, which is expected to commence in the fourth quarter of 2015.

About BL-7010

BL-7010 is a novel, non-absorbable, orally available co-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. This significantly reduces the immune response triggered by gluten. BL-7010 is excreted with gliadin from the digestive tract and is not absorbed into the blood. The safety and efficacy of BL-7010 have been 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. 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 Bellerophon BCM (f/k/a lkaria) and is in the midst of a pivotal CE-Mark registration trial scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML), and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

For more information on BioLineRx, please visit <u>www.biolinerx.com</u> 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 23, 2015. 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.

Source: BioLineRx Ltd.

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