



BioLineRx Completes Dose Escalation Stage of Phase 1/2 Study for Novel Celiac Treatment

March 10, 2014

Single administration of BL-7010 was safe and well tolerated at all doses tested

BL-7010 now advancing to repeated administration part of study; results expected mid 2014

JERUSALEM--(BUSINESS WIRE)--Mar. 10, 2014-- BioLineRx (NASDAQ: BLRX)(TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that the Company's novel treatment for celiac disease, BL-7010, has successfully completed the single administration, dose-escalation stage of the on-going Phase 1/2 clinical study. No serious adverse events were reported and there were no dose-limiting safety issues. Based on these positive safety and tolerability results, the Company will proceed with the repeated administration stage of the study. Results are expected in mid-2014.

The Phase 1/2 study, taking place at Tampere Hospital in Finland, a world-leading site for celiac disease research, is a two-part (single and repeated administration), double-blind, placebo-controlled, dose escalation study of BL-7010 in up to 24 well-controlled celiac patients. The primary objective of the study is to assess the safety of single and repeated ascending doses of BL-7010 in the study patients. Secondary objectives include an assessment of the systemic exposure, if any, of BL-7010 in the patients.

During the first part of the study, six dose levels of BL-7010 were evaluated compared to placebo. The escalation stage reached the highest planned dose, and although the study remains blinded at this point, no serious or dose-limiting adverse events were reported and all planned doses were found to be safe and well-tolerated. Consequently, all patients completed their participation in this part of the study. Based on these encouraging safety and tolerability results, the study will now progress to the repeated administration stage, in which each patient will receive either BL-7010 or placebo for 14 days, three times per day.

"BL-7010 for the treatment of celiac disease is one of our lead development programs, and we are very happy to see that it is safe and well tolerated - even at very high doses that are significantly above the expected clinical efficacious dose," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "BL-7010 is a unique and very promising product, with excellent pre-clinical efficacy and safety results. We expect to report the full results of the current Phase 1/2 study in mid-2014 and assuming they are successful, we expect to commence a randomized, controlled efficacy study in celiac patients by the end of this year."

"Celiac disease is highly prevalent throughout the world, with over 1% of the global population suffering from this disease. Nevertheless, there are currently no approved celiac therapies aside from a strict and lifelong gluten-free diet, which is exceptionally difficult and costly to maintain. Despite the significant need for new treatments, there are only a handful of clinical-stage projects under development worldwide for this disease, which we view as a significant opportunity for our product," concluded Dr. Savitsky.

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. This significantly reduces the immune response triggered by gluten. BL-7010 is excreted with gliadin from the digestive tract, preventing the absorption of gliadin into the blood. 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 Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; BL-7010 for celiac disease, which is in the midst of a Phase 1/2 study; and BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in the first half of 2014.

For more information on BioLineRx, please visit www.bioglinerx.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.

Source: BioLineRx

Tiberend Strategic Advisors, Inc.
Joshua Drumm, Ph.D., 212-375-2664
jdrumm@tiberend.com

or

Andrew Mielach, 212-375-2694
amielach@tiberend.com

or

Tsipi Haitovsky, Public Relations
+972-3-6240871
tsipih@netvision.net.il