



## BioLineRx Announces New Positive Results in Phase 2a trial for Orally Available Inflammatory Bowel Disease Treatment

November 26, 2013

**- New results show BL-7040 to reduce pro-inflammatory cytokine levels and improve colon histology in IBD patients BL-7040 was previously shown to be safe and effective in Phase 2a trial completed in Q2 2013 -**

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Jerusalem, November 26, 2013 - BioLineRx (NASDAQ: BLRX)(TASE:BLRX), a biopharmaceutical development company, announced today additional Phase 2a results showing significant improvement of disease measurements in biopsies taken from inflammatory bowel disease (IBD) patients treated with BL-7040, an orally available drug for treating IBD. The histological and biochemical analyses of inflammation indicators reinforce the initial positive results of the study, reported in April 2013, which showed that BL-7040 is safe and effective in treating ulcerative colitis, a form of IBD.

In order to perform the histological and biochemical analyses, biopsies were taken from trial participants before and after treatment. Biopsies from each time point were collected and randomly assigned to either a histological evaluation or to an assessment for levels of cytokines, considered as pro-inflammatory bio-markers. All analyses were performed in a blinded manner.

The histological results show that neutrophil levels were significantly reduced ( $p=0.002$ ) in patients treated with BL-7040. Neutrophils are the major cellular participant in acute inflammation, and their presence in the colon mucosa is believed to play a key role in causing tissue damage and clinical symptoms in IBD patients. Neutrophil levels are known to decrease when a patient's clinical condition improves. In this respect, all patients whose neutrophil levels were reduced also showed a clinical improvement as assessed by their Mayo score, the gold standard for assessing ulcerative colitis therapy.

An additional measure of disease severity is the level of the pro-inflammatory cytokine, interleukin 6 (IL-6). IL-6 is the predominant cytokine found in inflamed areas in ulcerative colitis patients, and its concentration correlates with the Mayo endoscopic score for disease severity. IL-6 levels were also significantly reduced ( $p=0.046$ ) in patients treated with BL-7040, and most patients with reduced cytokine levels showed clinical improvement.

"These positive results are an extension of the initial positive results of the Phase 2a trial for BL-7040, which showed that this promising drug is both safe and effective in treating ulcerative colitis. In fact, the clinical improvement in this trial was achieved after a relatively short treatment period, which leads us to believe that BL-7040 would have an even stronger beneficial effect after longer treatment duration," said Dr. Kinneret Savitsky, CEO of BioLineRx. "The new results, which show that BL-7040 significantly reduces inflammatory factors, such as neutrophils and cytokines, support BL-7040's mechanism of action – the ability to suppress the specific processes underlying the disease. Crohn's disease and ulcerative colitis, both forms of IBD, are prevalent conditions that affect the quality of life of millions of people across the globe. It is estimated that as many as 1.4 million persons in the United States suffer from these diseases. In addition to discomfort, which can be quite extreme, IBD can cause significant complications, including anemia, abscesses and more. Current treatments are far from satisfactory, and many people stand to benefit from a new and effective treatment for this condition. We believe that the positive results seen throughout the phase 2a study, as well its oral availability, make BL-7040 an attractive potential future treatment option."

### About the Phase 2a Study

The Phase 2a trial was an open-label, proof-of-concept study to evaluate the efficacy, pharmacodynamics, safety and tolerability of BL-7040 in patients with moderately active ulcerative colitis. Twenty-two patients were enrolled in the multi-center, proof-of-concept clinical trial, and 16 patients completed the study (five weeks of treatment plus two weeks of follow-up). During the five-week treatment period, patients received 12mg/day for up to three weeks, followed by 40mg/day for two additional weeks.

Statistical analyses were performed on the 16 patients completing five weeks of treatment, and the primary endpoint of clinical response was assessed by the Mayo score reduction between the last days of treatment compared to baseline. Fifty percent of patients met the primary endpoint, while the remaining patients demonstrated a stable clinical condition or minor improvement. Fifty-six percent of patients recorded a decrease in rectal bleeding of at least 1 point and 69% had a rectal-bleeding sub-score of  $\leq 1$  (and in six of these 11 patients no rectal bleeding was seen at all). Fifty percent of patients completing study treatment also met the secondary endpoint assessed by the partial Mayo score, while all other patients were clinically stable or demonstrated some improvement. Furthermore, 50% demonstrated mucosal healing evaluated by endoscopy sub-score measurements.

The drug was highly safe and well tolerated by the study participants, with very low incidence of drug related mild-moderate adverse events (AE) and one serious AE not related to BL-7040 treatment. Patients were very satisfied from the safety and tolerability profile of the treatment and emphasized the ease of oral administration.

### About BL-7040

BL-7040 is an orally available, synthetic oligonucleotide with a unique dual activity, being developed for the treatment of inflammatory bowel disease (IBD). It has a specific agonist effect on a receptor involved in the immune system and inflammatory reactions called Toll-Like Receptor 9 (TLR-9). It also acts as a specific suppressor of acetylcholinesterase, a key enzyme involved in neurological pathways. This dual effect enables a unique combination of both neurological and anti-inflammatory properties. In addition, BL-7040 has an indirect effect on the production of pro-inflammatory cytokines as well as anti-inflammatory properties via modulation of macrophages. BL-7040 was invented by Prof. Hermona Soreq from the Hebrew University of Jerusalem, and is being developed by BioLineRx under a worldwide exclusive license from Yissum Research and Development Company, the technology transfer company of the Hebrew University.

### About Inflammatory Bowel Disease (IBD)

Inflammatory bowel disease is a chronic inflammatory gastrointestinal disease characterized by chronic abdominal pain, discomfort, bloating and alteration of bowel habits. Over two million people are afflicted with IBD in the seven major markets. Sales of existing drugs in the seven major markets were estimated at over \$7.5 billion in 2012, of which \$5.6 billion were US-based sales. By 2020, sales in the seven major markets are expected to be

over \$8 billion, of which \$6.5 billion are expected to be in the US. Despite these numbers, there is still a significant portion of IBD patients who are underserved by current pharmacological treatments.

#### **About BioLineRx**

BioLineRx is a publicly-traded biopharmaceutical development company dedicated to building a portfolio of products for unmet medical needs, as well as those with advantages over currently available therapies. 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 is expected to commence a Phase 1/2 study in late 2013.

For more information on BioLineRx, please visit [www.biolineRx.com](http://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-7040, 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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