



BioLineRx Announces Positive Phase II Results for BL-7040, an Orally Available Treatment for Inflammatory Bowel Disease

April 17, 2013

- BL-7040 met the primary efficacy endpoint of the study -

- BL-7040 was also shown to be safe and well tolerated -

JERUSALEM--(BUSINESS WIRE)--Apr. 17, 2013-- BioLineRx (NASDAQ:BLRX) (TASE:BLRX), a biopharmaceutical development company, announced today positive Phase IIa results for BL-7040, an orally available drug for treating inflammatory bowel disease (IBD). The study showed that BL-7040 is safe and effective in treating ulcerative colitis, a form of IBD.

The Phase IIa trial was an open-label, proof-of-concept study to evaluate the efficacy, safety and tolerability of BL-7040 in patients with moderately active ulcerative colitis. Patients were treated for up to five weeks with BL-7040: 12 mg/day for up to three weeks, followed by 40 mg/day for two additional weeks. The clinical trial was carried out at five leading medical centers in Israel.

Sixteen of the 22 patients who were enrolled in the clinical trial completed the full five-week course of treatment and two-week follow-up. The primary clinical endpoint in the study - a reduction in the Mayo score between baseline and completion of treatment - was achieved. Fifty percent of patients (8 patients) met the primary endpoint, while the remaining 8 patients demonstrated a stable clinical condition or minor improvement. Fifty-six percent of patients (9 patients) demonstrated decreases of at least 1 point in the rectal-bleeding sub-score and 69% (11 patients) had rectal-bleeding sub-scores of ≤ 1 (in 6 of the 11 patients, no rectal bleeding was seen at all).

Fifty percent of the patients completing study treatment also met certain secondary endpoints, such as a partial Mayo score reduction and mucosal healing evaluated by endoscopy sub-score measurements. Additional secondary endpoints in the study were the IBD Quality-of-Life Questionnaire, and the serum CRP and fecal calprotectin measurements. The results of these additional secondary endpoints were not conclusive, although certain positive trends were noted.

BL-7040 was highly safe and well tolerated by the study participants, with a very low incidence of drug related, mild-to-moderate adverse events (AEs), as well as one serious adverse event (SAE) not related to the treatment. Both patients and investigators were very satisfied with the safety and tolerability profile of the treatment and, in particular, emphasized the ease of oral administration.

"Ulcerative colitis and Crohn's disease are prevalent conditions that affect the quality of life of millions across the globe. It is estimated that as many as 1.4 million individuals in the U.S. suffer from these diseases. In addition to discomfort, which can be quite extreme, IBD can cause significant complications, including anemia, intestinal abscesses, intestinal perforation and more. Current treatments are far from satisfactory, and many people stand to benefit from a new and effective treatment," said Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx.

"Based on historical data, current steroidal or biological treatment regimens have yielded clinical response rates of between 30% and 70% in studies with significantly longer treatment periods; thus, the results of our five-week, proof-of-concept study suggest positive efficacy for BL-7040. A number of experts in the IBD field who have reviewed the results of our study all agree that these are very encouraging and positive results, and that the reduction in rectal bleeding is particularly impressive. Our immediate next steps include evaluating the most advantageous ways to progress with this therapeutic candidate from a clinical and business perspective, including examining potential additional indications. In parallel, we also plan to accelerate discussions with potential co-development and licensing partners for this asset," concluded Dr. Savitsky.

About Inflammatory Bowel Disease (IBD)

IBD is a chronic inflammatory gastrointestinal disease characterized by chronic [abdominal pain](#), discomfort, bloating and alteration of bowel habits. Approximately 1-in-500 people worldwide suffer from IBD. The condition has few specific treatment options available. Sales of existing drugs are estimated at \$1.8 billion annually; however, current treatment options do not fully address patients' needs.

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-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-7040 for treating inflammatory bowel disease (IBD) has completed a Phase IIa trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase II study; BL-1021 for neuropathic pain is in Phase I development; and BL-1020 for schizophrenia. In addition, BioLineRx has six 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.bioglinerx.com, the content of which does not form a part of this press release.

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.

Source: BioLineRx

KCSA Strategic Communications
Garth Russell / Todd Fromer
1 212-896-1250 / 1 212-896-1215
grussell@kcsa.com / tfromer@kcsa.com

or

BioLineRx
Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsjih@netvision.net.il