



BioLineRx Receives Approval for Commencing Phase II Clinical Trial of BL-7040, an Orally Available Treatment for Inflammatory Bowel Disease

March 5, 2012

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[Hebrew version](#)

Jerusalem, March 5, 2012 - BioLineRx (NASDAQ:BLRX; TASE:BLRX) a biopharmaceutical development company, announced today that it has received approval from the Israeli Ministry of Health for commencing a Phase II clinical trial of BL-7040, an orally available molecule for treating Inflammatory Bowel Disease (IBD).

This Phase II trial will be an open-label study to evaluate the efficacy, pharmacodynamics, safety and tolerability of oral BL-7040 in up to 20 patients with moderately active ulcerative colitis, a type of IBD. Patients will be treated for up to five weeks with BL-7040: 12mg/day for up to three weeks followed by 40mg/day for two additional weeks. The clinical trial will be carried out at two sites in Israel: Sourasky Medical Center in Tel Aviv and Hadassah Medical Center in Jerusalem.

BL-7040 was shown to suppress inflammation in pre-clinical studies. In these studies, BL-7040 treatment led to amelioration of parameters associated with inflammatory bowel disease. BL-7040's efficacy in these studies was shown to be highly significant and comparable to that of dexamethasone, a steroid used routinely for IBD but which is associated with multiple side effects. BL-7040's safety was also demonstrated in pre-clinical studies, as well as in previous clinical trials.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, "We are eagerly anticipating the commencement of this clinical trial on BL-7040's efficacy which, if successful, could herald a breakthrough in the treatment of IBD. Many of today's treatments have severe side effects and are not effective in up to 40% of patients. BL-7040 is an orally available treatment for Inflammatory Bowel Disease with a novel mechanism of action, which we believe will have greater efficacy and an improved safety profile."

About Inflammatory Bowel Disease (IBD)

IBD is a chronic, inflammatory, gastrointestinal disease characterized by chronic abdominal pain, discomfort, bloating and bleeding. The two major types of IBD are ulcerative colitis (UC) and Crohn's disease. There are a variety of treatment options available for IBD but all these treatments are associated with significant side effects. In addition, 25-40% of patients do not respond to treatment. Therefore, there remains a significant unmet medical need for novel, efficacious treatments with a favorable safety profile.

In 2009 the IBD population was estimated at 2.3 million in the seven major markets (US, Japan, France, Germany, Italy, Spain and UK) and is forecasted to grow to 2.9 million in 2019. The IBD market in the seven major markets was estimated at \$3.5 billion in 2009 and is forecasted to grow to \$5.6 billion in 2019.

About BioLineRx

BioLineRx Ltd. 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 five clinical stage candidates: BL-1020 for schizophrenia has completed a Phase IIb study; BL-1040, for treatment of patients following a myocardial infarction, which has been out-licensed to Icaria 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-1021 for neuropathic pain is in Phase I development and BL-7040 for treating Inflammatory Bowel Disease (IBD) is commencing a Phase II trial. In addition, BioLineRx has thirteen products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, 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.biolinerx.com.

Various statements in this release concerning BioLineRx's future expectations, plans and prospects, including, without limitation, statements relating to the ability to develop and commercialize the BL-7040 project, 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 Form F-1 filed with the Securities and Exchange Commission on February 29, 2012. 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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