



## BioLineRx Announces First Subject Enrolled in Phase I Clinical Trial of BL-1021 for Neuropathic Pain

July 5, 2011

**Jerusalem, July 5, 2011** - BioLineRx (TASE:BLRX) announced today the enrollment of the first subject in a Phase I study of BL-1021, an orally available small molecule for treating neuropathic pain. This clinical trial will be a first-in-human, single-site, double-blind, placebo controlled study to assess safety, tolerability and pharmacokinetics of BL-1021 in healthy volunteers. The primary endpoints of the study are to examine the safety and tolerability of a single administration or multiple administrations of BL-1021, and the secondary endpoints are the pharmacokinetics of single or multiple doses of BL-1021 in healthy subjects. The study will be carried out at the Hadassah Clinical Research Center (HCRC) in Jerusalem, Israel, led by Principal Investigator Professor Yoseph Caraco, and is expected to enroll up to 56 subjects.

Dr. Kinneret Savitsky, BioLine's CEO, stated, "We are excited about commencing a clinical study to more fully characterize the therapeutic potential of BL-1021. Based on the promising results from our pre-clinical studies, we believe it has the potential to provide improved efficacy without the side effects associated with many existing medications. This is an important next step towards potentially making BL-1021 available as a treatment for neuropathic pain, which causes great suffering among millions of patients throughout the world, including diabetics and cancer patients."

### **About BL-1021**

BL-1021 is an orally available small molecule for the treatment of neuropathic pain and was designed to target the activities of anti-neuropathic antidepressant drugs without their common adverse effects. Pre-clinical studies performed to date suggest that BL-1021 is an effective compound in animal models of neuropathic pain. The data demonstrate that BL-1021 has a lowered propensity for sedation, no cardiac toxicity and improved efficacy compared with other anti-pain medications.

### **About Neuropathic Pain**

Neuropathic pain is a complex, chronic state of pain that results from dysfunctional or injured nerve fibers. Neuropathic pain is associated with various conditions, including shingles, diabetes and cancer and is reported to affect 1% to 3% of the population. Patients describe the symptoms as burning, stabbing, electric shock or itching sensations, which can cause extreme discomfort for extended periods of time. A variety of medications are used to treat neuropathic pain, including antidepressants and anti-seizure medicines. However, these medications have significant side effects and are not always effective. In 2009 the neuropathic pain market was estimated to be \$2.4 billion in the seven major markets (US, Japan, France, Germany, Italy, Spain and the UK), and it is projected to grow to \$4.1 billion in 2018.

### **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 is in Phase II/III clinical trials; BL-1040 for treatment of patients following a myocardial infarction has completed a Phase I/II study and has been out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties; 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) has completed Phase I. In addition, BioLineRx has nine 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](http://www.biolinerx.com).

### **Forward Looking Statement**

*The estimates and judgments with respect to the projects included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates, including clinical trial commencement dates, may not be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.*

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