



BioLineRx Announces Positive Final Results from Phase Ia Clinical Trial of BL-1021 for Neuropathic Pain

December 6, 2011 7:52 AM IST

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[Hebrew version](#)

Jerusalem, December 6, 2011 - BioLineRx (NASDAQ:BLRX) (TASE:BLRX) announced today the final results of the Phase Ia study of BL-1021, an orally available small molecule for neuropathic pain. In this study it was demonstrated that a single administration of BL-1021 in the dose range examined was safe and well tolerated, with no significant changes noted in vital signs, ECG or laboratory safety parameters at any dose when compared either to baseline measurements or to the placebo group. In addition, BL-1021 demonstrated a favorable pharmacokinetic profile and the potential for once daily oral administration. In September 2011, BioLineRx announced positive interim results from the trial.

The trial was a double-blinded, placebo-controlled study performed at the Hadassah Clinical Research Center in Jerusalem, Israel, led by Principal Investigator Professor Yosef Caraco. The study aimed at assessing the safety, tolerability and pharmacokinetics of a single administration of BL-1021 (between 10 mg and 80 mg) in healthy male subjects.

Dr. Kinneret Savitsky, BioLineRx's CEO, stated, "This study has clearly demonstrated that BL-1021 is a safe, well-tolerated drug. We have only observed mild, transient, adverse events with similar incidence to those observed in the placebo group. We are very encouraged by these results, which indicate that BL-1021 has potential as an effective treatment for neuropathic pain with minimal side effects and requiring only once daily dosing. This could mean new hope for the millions of people around the world suffering from neuropathic pain. We are now evaluating the next steps for BL-1021 from both a scientific and a commercial perspective, including a possible narrowing of the indication."

About BL-1021

BL-1021 is an orally available small molecule for the treatment of neuropathic pain that was designed to have similar activities to other anti-neuropathic drugs without their common adverse effects. BL-1021's efficacy has been demonstrated in various animal models of neuropathic pain. Pre-clinical data demonstrate that BL-1021 has a lowered propensity for sedation, low 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 2010 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 prevention of pathological cardiac remodeling 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 trials; 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.bioglinerx.com.

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 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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