BioLineRx Announces Receipt of Approval in India to Commence Phase II/III CLARITY Clinical Trial of BL-1020 for Treatment of Schizophrenia

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Hebrew Version

Jerusalem, November 22, 2011 - BioLineRx (NASDAQ:BLRX; TASE:BLRX), a biopharmaceutical development company, announced today that it has received approval from the Indian regulatory authorities and the Indian local ethics committees to commence the Phase II/III CLARITY clinical trial of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia. In June 2011, BioLineRx announced the commencement of patient enrollment in the CLARITY trial in Romania, which is currently ongoing according to schedule.

The Initiation Visits at the first few Indian clinical research centers will be completed in November, with enrollment of the first patient expected in December. Additional centers in India will also be joining the trial over the coming weeks. Overall, the trial is expected to be conducted at approximately 18 sites in India, 14 sites in Romania and four sites in Israel.

"The approval to commence the trial in India represents an important milestone in the progress of the BL-1020 CLARITY trial. In addition, we are also intending to submit in the near future a regulatory package to the authorities in Israel in order to open four Israeli sites for our clinical trial. The trial, if successful, will support BL-1020's unique potential as an antipsychotic therapy that also improves cognition," stated Dr. Kinneret Savitsky, CEO of BioLineRx. "We look forward to announcing top-line results from the CLARITY trial in early 2013. Also, concurrent with the progress of the trial and in accordance with our business strategy, we have renewed our efforts to seek an out-licensing partner to continue development and commercialization of BL-1020."

The CLARITY trial is a randomized, double-blinded, positive-controlled study that will enroll up to 450 patients experiencing an acute exacerbation of schizophrenia. The goal of the study is to determine the short-term and long-term cognitive efficacy as well as the anti-psychotic efficacy, safety and tolerability of BL-1020 in schizophrenia patients, over periods of six, 12 and 24 weeks. Risperidone, an approved and widely used schizophrenia drug, serves as the positive control for antipsychotic efficacy. The cognition primary endpoint measure will utilize the MATRICS Cognitive Consensus Battery (MCCB), and cognitive benefit will be assessed by comparing the change from baseline in total MCCB score, comparing BL-1020 to Risperidone at the landmarks of six, 12 and 24 weeks. The original protocols for the study included a placebo arm for the first six weeks of the study; however, this arm was removed from the protocols at the request of the regulatory authorities.

About BL-1020
BL-1020 is a novel, first in class, oral therapeutic for schizophrenia. Pre-clinical and clinical trials to date have shown that BL-1020 is effective at treating schizophrenia symptoms and has a good safety profile. These trials have shown that BL-1020 blocks activity of the neurotransmitter dopamine and enhances the activity of another neurotransmitter, GABA. These characteristics may contribute to the efficacy and safety of the drug. In addition, clinical trials have shown that BL-1020 improves cognitive function in schizophrenia patients. Many schizophrenia patients suffer from a significant decrease in cognitive function, which is an unmet medical need not addressed by current therapies.

About Schizophrenia
Schizophrenia is a chronic, severe mental disorder which affects approximately 1% of the population worldwide. It is characterized by hallucinations, delusions and disorganized thoughts. In addition, many schizophrenia patients suffer from cognitive impairment, which affects their ability to function and lead normal lives. The antipsychotic therapeutic market recorded sales of $13.6 billion in the U.S. alone in 2008.

About BioLineRx
BioLineRx Ltd. is a publicly-traded biopharmaceutical development company. It 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 commenced a Phase II/III study; 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.

The estimates and judgments with respect to BL-1020 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 and results 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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