



BioLineRx Announces First Patient Enrolled in Phase II/III CLARITY Clinical Trial for BL-1020, a First in Class GABA-Enhanced Antipsychotic Treatment for Schizophrenia

June 28, 2011

Jerusalem, June 28, 2011 - BioLineRx (TASE:BLRX), a biopharmaceutical development company, announced today the enrollment of the first patient in the Phase II/III CLARITY clinical trial of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia.

The CLARITY trial is designed as a randomized, double-blind, placebo-controlled study and is expected to be conducted in 15 sites in Romania and 19 sites in India, on a total of 435 patients experiencing an acute exacerbation of schizophrenia. The primary endpoints of the study are to determine the short-term cognitive benefit and anti-psychotic efficacy, safety and tolerability of BL-1020 in schizophrenia patients, over a period of 6 weeks, compared with Risperidone, an approved atypical schizophrenia drug, and placebo. Determination of the long term effects of the drug, over a period of 24 weeks, is a secondary endpoint.

"It is generally accepted that the most important domains of neurocognitive functioning that are impaired in people with schizophrenia are working memory, attention, verbal and visual learning, reasoning and social cognition. There is a clear need for new antipsychotic drugs that are effective and improve cognition," commented Richard Keefe, Ph.D., Professor of Psychiatry and Behavioral Sciences and Psychology at Duke University Medical Center. "Results of clinical and nonclinical trials to date suggest that BL-1020 has the potential to be an efficacious anti-schizophrenic drug while also improving cognition."

"The initiation of the CLARITY trial represents a very positive and important step towards the commercialization of BL-1020. We expect to report results from the trial in the fourth quarter of 2012, and if this trial is successful, it will further demonstrate BL-1020's unique properties of improving both schizophrenia symptoms and cognition," stated Dr. Kinneret Savitsky, BioLineRx's CEO. "Currently, there is no schizophrenia treatment available that also improves cognition, so this represents an important unmet medical need for patients suffering from this disorder. We believe that BL-1020, with its unique properties, especially improvement of cognitive function, will become a significant advance in the treatment of people suffering from schizophrenia."

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 US alone in 2008.

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 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.

Forward Looking Statements

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.