BioLineRx Announces Publication of EAGLE Study Results Demonstrating BL-1020's Efficacy in Improving Cognitive Function in Schizophrenia Patients

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– Results of Phase IIb clinical trial from September 2009 now published in the Journal of Clinical Psychiatry –

– BL-1020 is currently undergoing Phase II/III CLARITY clinical trial with results expected in H2 2013 –

JERUSALEM--(BUSINESS WIRE)--Sep. 27, 2012-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today the publication of results from the Phase II EAGLE clinical trial for BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia, showing that BL-1020 is safe and effective in improving schizophrenia, in addition to improving cognitive impairment associated with this condition. The findings, which were originally announced in September 2009, were published in the September 2012 issue of the Journal of Clinical Psychiatry.

"Significant cognitive impairment is very common in schizophrenia, affecting the great majority of patients, yet currently available antipsychotics have not been effective in treating core cognitive impairment for people suffering from this disease. In fact, two recent landmark studies, in first-episode patients and in chronically ill patients, did not find first- or second-generation antipsychotics to be significantly effective in ameliorating cognitive impairment," explained Richard Keefe, Ph.D., Professor of Psychiatry and Behavioral Sciences and Psychology at Duke University Medical Center, and co-author of the Paper. "Cognitive impairments are important targets for intervention, as they affect vocational and social functioning and independent living. Therefore, there is a clear need for new antipsychotic drugs that are effective and that improve cognition. In the Phase IIb EAGLE study, BL-1020 shows a clear and significant effect in improving cognitive function in schizophrenia patients."

The Paper describes the results of the Phase IIb EAGLE study for determining safety, efficacy, and tolerability of low (10 mg/d) and flexible high (20–30 mg/d) doses of BL-1020 compared to Risperidone, an approved atypical schizophrenia drug, and placebo. Results of the study shows that BL-1020 was significantly better than the placebo and comparable with Risperidone in both PANSS and CGI scores, which are widely recognized measures of severity and improvement in schizophrenia. More importantly, the results show a significant improvement in cognitive function as assessed by BACS (Brief Assessment of Cognition in Schizophrenia), when compared to both placebo and Risperidone.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, "We are pleased with the publication of the EAGLE trial results in a leading scientific journal. Nearly 1% of the world's population suffers from schizophrenia, which often involves cognitive impairment that may severely undermine daily living skills. Current schizophrenia therapies do not address cognitive impairment, whereas the EAGLE clinical trial shows that BL-1020 significantly enhances cognitive function in schizophrenia patients and therefore has the potential to enhance the functionality and independent living skills of patients with schizophrenia. In order to further validate these results, we are currently conducting the CLARITY clinical trial, which assesses cognition enhancement by BL-1020 as its primary objective. We look forward to the expected results in the second half of 2013."

About BL-1020

BL-1020 is a first-in-class GABA-enhanced antipsychotic that combines dopamine antagonism with GABAergic activity. BL-1020 has demonstrated high efficacy and safety with minimal EPS and no metabolic side effects. Most importantly, BL-1020 may have the potential to improve cognition, which is a significant unmet medical need in schizophrenia and other neurological/psychiatric disorders. Three clinical studies have confirmed the safety and efficacy of BL-1020, while pre-clinical studies have also shown that BL-1020's GABA enhancement may provide the basis for improved cognition.

In June 2011, BioLineRx announced commencement of the Phase II/III CLARITY clinical trial of BL-1020. This 450-patient trial aims to determine the short-term (6 weeks) and the long-term (24 weeks) cognitive benefit and anti-psychotic efficacy, safety and tolerability of BL-1020 in schizophrenia patients, compared with Risperidone (one of the leading schizophrenia treatments). The CLARITY trial is proceeding at approximately 30 sites in Romania and India.

About Schizophrenia

Schizophrenia is a serious mental disorder that affects about 1% of the world's population. It is a multi-factorial disease characterized by delusions and hallucinations, emotional withdrawal and apathy, poor attention and disorganization. The worldwide antipsychotic therapeutic market in 2011 was estimated at approximately $20 billion.

About BioLineRx

BioLineRx 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 six clinical stage candidates: BL-1020 for schizophrenia is currently undergoing a Phase II/III study; BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria 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, BL-7040 for treating inflammatory bowel disease (IBD) has commenced a Phase II trial, and BL-8040 for treating acute myeloid leukemia (AML) 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, 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, including specifically those related to the development and commercialization of BL-1020, 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 most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 22, 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.

Source: BioLineRx

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