# BioLineRx to Conduct Interim Analysis of Phase II/III CLARITY Clinical Trial of BL-1020 for Treatment of Schizophrenia

October 24, 2012

***– Results of interim analysis expected in Q1 2013 –***

JERUSALEM--(BUSINESS WIRE)--Oct. 24, 2012-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that it intends to conduct an interim analysis of the Phase II/III CLARITY trial of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia. The interim analysis, which is expected to be finalized in the first quarter of 2013, will be performed on data of approximately 235 randomized patients from 27 sites in Romania and India. The primary endpoint of the analysis will be the six-week effect of the drug on cognitive function, which is a principal deficit in schizophrenia patients.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, “The recent re-analysis of BL-1020's EAGLE Phase IIb study, showing a substantially greater beneficial effect of the drug on cognitive function in schizophrenia patients, as compared to the original analysis of the study, has increased our confidence in the potential of this first-in-class drug candidate. This, together with other positive ad-hoc analyses, as well as BL-1020's excellent track record in both clinical and pre-clinical studies, has prompted us to initiate an interim analysis of the on-going CLARITY Phase II/III trial. Assuming the recruitment rate continues as planned, we expect to conduct a meaningful interim analysis of the short-term cognitive effects of BL-1020 on schizophrenic patients in the first quarter of next year. We hope that the results will reinforce our confidence regarding the cognitive benefits of the drug, and if so, will enable us to expedite our commercialization efforts for the further development of this promising therapeutic candidate. We are eagerly looking forward to the results of the interim analysis."

Earlier this month, the Company announced that a recent re-analysis of the results of the Phase IIb EAGLE clinical trial of BL-1020 showed that, when taking into account effects of the circadian rhythm (i.e., 24-hour time cycle) on cognitive function of the subjects, BL-1020 is even more potent in improving cognitive function than initially thought. The ramifications of this re-analysis have been taken into account in the execution of the CLARITY trial.

**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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