



BioLineRx Announces New Analysis of EAGLE Phase IIb Study Showing a Significantly Greater Beneficial Effect of BL-1020 on Cognitive Function in Schizophrenia Patients

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

JERUSALEM--(BUSINESS WIRE)--Oct. 9, 2012-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that a recent analysis of the results from the Phase IIb EAGLE trial for BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia, indicates that BL-1020 demonstrated a significant increase in efficacy at improving cognitive impairment associated with this condition, as compared to the original analysis of the study.

The findings pertain to the results of the Phase IIb EAGLE study, first published in September 2009, for determining safety, efficacy, and tolerability of BL-1020 compared to Risperidone, an approved atypical antipsychotic drug, and placebo. Results of the study showed 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. In addition, the results showed a statistically significant improvement in cognitive function as assessed by BACS (Brief Assessment of Cognition in Schizophrenia), when compared to both placebo and Risperidone.

Recently, an outside research group performed a further analysis of the results of the EAGLE study, which specifically take into account effects of the circadian rhythm (i.e., 24-hour time cycle) on cognitive function of the subjects. Results of the re-analysis clearly show that when the time of day for administration of the neurocognitive BACS test was consistent between visits, the beneficial effect of BL-1020 on cognitive function was even more pronounced than the original analysis. Specifically, the original analysis for all patients in the study showed an effect size of 0.40 for BL-1020 versus placebo and an effect size of 0.39 for BL-1020 versus Risperidone. However, according to the re-analysis, for the subset of patients with consistent testing times, the effect size increased significantly, to 0.97 for BL-1020 versus placebo and 0.57 for BL-1020 versus Risperidone. These results mean that the beneficial effect of BL-1020 on cognitive function, when compared to the original analysis, more than doubled versus placebo and increased by almost 50% versus Risperidone.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, "Cognitive functioning is influenced by circadian rhythms over the course of the day, and patients with schizophrenia are known to have profoundly disturbed circadian rhythms that can affect their cognitive functioning. Therefore, a new analysis was performed to determine whether taking into account consistency in the timing of neurocognitive testing between the baseline and endpoint visits could affect assessment of the efficacy of BL-1020. This analysis found that when the baseline and endpoint visits were conducted at the same time of day, there was a significantly more robust treatment response as compared to those patients where the timing of the visits was inconsistent. These findings indicate that BL-1020 is even more efficient at improving cognitive function than was previously shown."

"We are very excited with these new findings by an outside group of leading scientists relating to the EAGLE trial. The results not only show an increased efficacy of BL-1020 in improving cognitive function in schizophrenia patients, but also have positive implications on conducting and analyzing the ongoing CLARITY trial, which is specifically designed for assessing BL-1020's cognition enhancement effect," concluded Dr. Savitsky.

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 Icaria 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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