



## **BioLineRx Announces Positive Results from Its Phase 2b EAGLE Extension Trial Assessing the Safety and Efficacy of BL-1020**

January 17, 2010

Jerusalem, Israel, January 17th, 2010: Following our previous press releases (published September 14th and 23rd, 2009) announcing that BL-1020 has successfully met its primary and secondary efficacy endpoints, as well as significantly improved cognition in the 6-week phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) trial, we are pleased to report positive results from the 6-week extension trial.

The new results show that patients receiving BL-1020 (20-30mg/day) for 6 additional weeks maintained the improvements in PANSS and CGI (widely recognized measures of severity and improvement in schizophrenia) after 6 weeks of treatment and, more importantly, showed an additional improvement in cognitive function as assessed by BACS ("Brief Assessment of Cognition in Schizophrenia"). The 12-week treatment was not associated with any increased toxicities - there were no clinically relevant changes in the measurements of the ECG, laboratory or vital signs (BP, HR, Temp). In addition, patients treated with 20-30mg/day BL-1020 showed either no change or a reduction in their Extra-Pyramidal Symptoms Rating Scale (ESRS).

These results strengthen previous findings and show that longer term BL-1020 treatment is safe, effective and has the potential to improve cognition in schizophrenia patients.

Dr. Kinneret Savitsky, PhD - CEO of BioLineRx, states: "We are very pleased with the findings of the extension trial. These results strengthen our belief that BL-1020 may provide great benefit and relief to schizophrenia patients and their families. The additional positive results should strengthen the basis for collaboration with a global pharmaceutical company in order to complete BL-1020's development. We are grateful to the inventors and their academic affiliations, Prof. Abraham Nudelman (department of Chemistry, Bar-Ilan University), and Prof. Abraham Weizmann, Dr. Ada Rephaeli and Dr. Irit Gil-Ad (Faculty of Medicine, Tel Aviv University)".

### **About EAGLE Main and Extension Trials**

The EAGLE study was conducted under a U.S. Food and Drug Administration Investigational New Drug (IND) at 40 sites in the U.S., Europe and India, and included patients suffering from acute exacerbation of schizophrenia. In the main 6-week study, 363 patients were randomized to treatment with 10 mg/day or 20-30mg/day of BL-1020, Risperidone (2-8mg/day) or placebo. The study was designed to demonstrate statistically significant superiority of BL-1020 to placebo on the primary efficacy measure, the total score of the Positive and Negative Symptom Scale (PANSS). Key secondary efficacy measures included the Clinical Global Impression of Severity (CGI-S), the Clinical Global Impression of Change (CGI-C) from baseline, and effect on cognition as measured by the Brief Assessment of Cognition in Schizophrenia (BACS). Risperidone was included as a positive control to validate the study results.

The 6-week extension trial involved patients that completed the main study. 75 patients were randomized as follows: patients that were treated with BL-1020 (10 or 20-30mg/day) or Risperidone continued their treatment; patients that were treated with placebo were re-randomized to one of the BL-1020 groups.

### **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 other 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.

### **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 current global schizophrenia market is \$13 billion. Based on marketing studies commissioned by BioLineRx, BL-1020 with its current safety and efficacy profile may be able to capture as much as 25% of this market.

### **About BioLineRx**

BioLineRx, a clinical stage drug development company traded on the Tel Aviv Stock Exchange (TASE: BLRX), is dedicated to building a robust pipeline of promising therapeutics for unmet medical needs. The Company's leading programs are BL-1020 for the treatment of schizophrenia and BL-1040 for the treatment of damaged heart tissue following acute myocardial infarction. BL-1040 has recently been out-licensed to Ikaria for a total deal value of \$282.5 million. Additional products under development

include clinical and pre-clinical compounds for various indications. For more information, please visit [www.biogener.com](http://www.biogener.com).