BioLineRx Announces Positive Topline Results for BL-1020, a First in Class GABA Enhanced Antipsychotic for the Treatment of Schizophrenia

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BL-1020 meets primary and secondary efficacy endpoints from the phase 2b EAGLE trial

Jerusalem, Israel, September 14th, 2009- BioLineRx announced today top line results from its phase 2b EAGLE (Effective Antipsychosis via GABA Level Enhancement) study assessing the efficacy, safety and tolerability of BL-1020, conducted under a US FDA IND (Investigational New Drug).

This randomized, placebo and active control double-blind phase 2b trial demonstrated statistically significant superior efficacy of BL-1020 on the primary study efficacy end-point as well as on the key efficacy measures compared to placebo. Preliminary analysis indicates superiority of BL-1020 in cognitive function as compared to placebo and Risperidone. BL-1020 was well tolerated and did not show any increased safety risk as compared to placebo. Additional analyses are ongoing and will be released as soon as they become available. The full study results will be presented at a forthcoming scientific meeting.

The primary efficacy measure in the EAGLE study was improvement from baseline of the total PANSS (Positive and Negative Symptom Scale) score utilizing an intent to treat (ITT) population model. The results show that the BL-1020 High Dose group (20-30mg/day) caused a statistically significant reduction in PANSS versus Placebo (LS mean -23.6 vs. -14.4; p=0.002).

The superiority of BL-1020 (20-30mg/day) over placebo was also supported by additional secondary efficacy measures such as CGI-S and CGI-C in hospitalized patients with acute schizophrenia. Furthermore, statistically significant increases in the number of patients rated as ‘responders’ in the BL-1020 (20-30mg/day) group as compared to placebo on the PANSS, CGI-S, and CGI-C, was in line with all other efficacy measures.

Most promising, preliminary analysis of the effect of BL-1020 on cognition provided evidence of benefit. Analysis of the Brief Assessment of Cognition in Schizophrenia (BACS) composite scores indicated superiority of BL-1020 as compared to placebo and Risperidone on day 42. This data is still being analyzed and further information will be released as it becomes available.

Analysis of safety did not indicate any increased toxicity associated with BL-1020 treatment. The incidence of SAEs (Severe Adverse Events) was low in the BL-1020 (20-30mg/day) group (0%) compared to Risperidone (3.3%) and placebo (6.5%). Discontinuations due to AEs (Adverse Events) were similar in the BL-1020 (20-30mg/day) group and in the placebo group (4.3%) but higher in the Risperidone group (8.8%). There were no statistically significant or clinically relevant AEs of body weight gain, glucose increases, and changes in lipids, all indicating that BL-1020 has no metabolic AE propensity. BL-1020 at its high dose level induced a slight increase in the Extra-Pyramidal Symptoms Rating Scale (ESRS) that did not differ significantly from Risperidone (a second generation antipsychotic-SGA). The incidence of cardiovascular, sexual, psychiatric, autonomic and gastrointestinal AEs was low and not increased compared to placebo. There were no statistically significant or clinically relevant changes in the measurements of the ECG, laboratory or vital signs (BP, HR. Temp).

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 EAGLE
The EAGLE study was conducted under a U.S. Food and Drug Administration Investigational New Drug (IND) at approximately 40 sites in the U.S., Europe and India and included patients suffering from acute exacerbation of schizophrenia. In this six-week study, 363 patients were randomized equally to treatment with low (10 mg/day) or high (20-30mg/day) dose 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 at a dose of 2-8 mg was included as a positive control to validate the study results.

Dr. Morris Laster MD, CEO of BioLineRx, states: “We are very excited with these findings. These results solidify our belief that BL-1020 may provide great benefit and relief to schizophrenia patients and their families. We are hopeful that the positive phase 2b EAGLE study results will form the basis for collaboration with a global pharmaceutical company, in order to complete BL-1020’s development and enter the market for the benefit of schizophrenia patients and their families. With these results BioLineRx continues to fulfill its strategic mission of “bench to bedside to market” based on novel therapeutics primarily derived from Israeli academia. We are grateful to the inventors and their academic affiliations, Prof. Abraham Nudelman (department of Chemistry, Bar-Ilan University), and Prof. Abraham Weizman, Dr. Ada Rephaeli and Dr. Irit Gil-Ad (Faculty of Medicine, Tel-Aviv University)”.

Dr. Ravi Anand MD, a world renowned schizophrenia expert who was previously Executive Director and Head of CNS Clinical Trials at Organon NV, and a consultant to BioLineRx, states: "The results of the EAGLE study are very exciting as they provide clinical validation of its pre-clinical results and mechanism of action. These results indicate broad anti-psychotic efficacy and safety of BL-1020, equivalent to Risperidone - the most effective and safe SGA, and the world’s most prescribed antipsychotic. The early signs that indicate BL-1020 has a positive effect on cognition, an attribute not shown for any other anti-psychotic, are very promising. A new treatment that would ameliorate psychotic symptoms and improve cognition would represent a major therapeutic advance for patients with schizophrenia.”

Professor Michael Davidson MD, Chairman of Psychiatry Tel Aviv University and BioLineRx consultant, states: “Persistent and treatment refractory cognitive impairment is present in the majority of schizophrenia patients and contributes to social and vocational deficit more than psychosis. None of the currently available atypical antipsychotic drugs presents any advantage over the older typical drugs in improving cognition as demonstrated by the publicly funded CATIE and EUFEST trials. In the current study, BACS scores measuring cognitive functions improve in the group treated with 20-30mg/day BL-1020 group, but not in the groups treated with Risperidone or placebo. These results confirm our pre-clinical findings and support the

hypothesis that GABA has a role in enhancing cognitive functioning."

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 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.biolinerx.com.