EAGLE Trial Signals Breakthrough in the Treatment of Schizophrenia

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Jerusalem, Israel: Following our previous press release (published September 14th, 2009) announcing that BL-1020 has successfully met its primary and secondary efficacy endpoints from the phase 2b EAGLE (Effective Anti-psychosis via GABA Level Enhancement) trial, we are pleased to report positive final results regarding the effects of BL-1020 on cognition.

Patients with schizophrenia suffer from significant cognitive dysfunction. This is reflected in difficulty of daily functioning, decreased ability to maintain a normal social relationships and impaired job performance. Currently available antipsychotics have not been shown to improve cognition.

Cognitive function in the EAGLE trial was measured by the “Brief Assessment of Cognition in Schizophrenia” (BACS). The BACS test comprises the following six components: verbal memory, digit sequencing, token motor task, verbal fluency, symbol coding and the “Tower of London” puzzle. All of these functions are significantly impaired in patients with schizophrenia.

The EAGLE trial results indicate that patients treated for six weeks at the 20-30mg dose of BL-1020 exhibited a clinically relevant and statistically significant improvement of 9.27 points in the BACS score as opposed to the placebo control group (6.01 points) and the Risperidone group (6.2 points). BL-1020 exhibited statistical significance to both the placebo and Risperidone control groups ($p=0.027$ for both).

These results constitute a breakthrough in the treatment of patients with schizophrenia. BL-1020 offers for the first time, high efficacy, an improved safety profile and improved cognitive function.

The global anti-psychotic drug market is expected to reach approximately $17 billion by 2016. According to a comprehensive market research report prepared for BioLineRx, based on its’ profile, BL-1020 could capture 20-30% of this market. In addition, we believe that BL-1020 could be beneficial for other neurological/psychiatric disorders that affect cognitive function. The global market for compounds that may improve cognition is estimated at $20-30 billion.

Professor Michael Davidson MD, Chairman of Psychiatry, Tel Aviv University and consultant to BioLineRx, states: “Persistent and treatment refractory cognitive impairment is present in the majority of schizophrenia patients and contributes to social and vocational impairment even more than psychosis. Improving cognition remains a significant unmet medical need. The results of the double blind EAGLE clinical trial showed that while the cognitive function of patients treated with BL-1020 improved, patients treated with Risperidone and placebo did not.”

Richard Keefe, PhD, Professor of Psychiatry and Behavioral Sciences at Duke University, CEO of NeuroCog Trials, Inc., and consultant to BioLineRx, states: “In this double-blind trial, patients treated with the 20-30mg dose of BL-1020 demonstrated greater improvement in cognition as measured by the Brief Assessment of Cognition in Schizophrenia score than either Risperidone or placebo. The amount of improvement with BL-1020 compared to the other treatments was large enough to be not only statistically significant, but clinically significant as well.”

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 has now been shown to clinically 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 the improved cognition seen in the clinic.

BioLineRx has obtained a worldwide exclusive license for BL-1020 from Bar-Ilan Research and Development Company Ltd. and Ramot at Tel Aviv University Ltd. BL-1020 was invented by Prof. Abraham Nudelman (Department of Chemistry, Bar-Ilan University), Dr. Ada Rephaeli, Prof. Abraham Weizman and Dr. Irit Gil-Ad (Faculty of Medicine, Tel-Aviv University).

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.

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.

About NeuroCog Trials
NeuroCog Trials, Inc. is a cognition services company devoted to applying academic-quality standards to training, certification, and data quality assurance for neurocognitive outcomes in multi-site clinical trials. The company has overseen the neurocognitive assessment procedures for over 50 national and international multi-site clinical trials working with a variety of pharmaceutical companies and academic consortia. NeuroCog Trials has certified over 2000 neurocognitive testers and assured data quality for over 30,000 assessments using various assessment tools, including the Brief Assessment of Cognition in Schizophrenia (BACS), MATRICS Consensus Cognitive Battery (MCCB), Brief Assessment of Cognition in Affective Disorders (BAC-A), Brief Assessment of Cognition (BAC), the UCSD Performance-based Skills Assessments (UPSA, UPSA-B) and Schizophrenia Cognition Rating Scale (SCoRS). NeuroCog Trials has the exclusive rights to license the BACS and related instruments, the SCoRS, and all UPSA versions. Please visit www.neurocogtrials.com.