



BioLineRx Provides Clarification Regarding Interim Analysis of CLARITY Trial for BL-1020

February 4, 2013

JERUSALEM--(BUSINESS WIRE)--Feb. 4, 2013-- BioLineRx Ltd. (NASDAQ: BLRX)(TASE: BLRX), a biopharmaceutical development company, notes that, as previously disclosed, results from the interim analysis of the Phase II/III CLARITY clinical trial of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia, are expected to be reported during the week of March 18, 2013. The CLARITY trial is a randomized, double-blind trial to examine acute (6 weeks) and long-term (24 weeks) cognitive and antipsychotic efficacy, safety and tolerability of BL-1020 on patients with acute schizophrenia. The interim analysis will be performed on data of approximately 235 randomized patients from 27 sites in Romania and India.

The interim analysis will be performed by a fully independent, external Data Monitoring Committee (DMC), which will maintain complete blinding of all study data from the Company. As a result of the analysis, the DMC will provide the Company with an estimate of the total number of patients required in the study in order to achieve statistical significance on the cognitive endpoints of the study.

The Company hereby emphasizes that as the CLARITY trial is on-going and given the double-blind trial design, BioLineRx at present has no insight into the results of the interim analysis. Any media reports or comments by those outside of the Company regarding the outcome of the interim results of the CLARITY trial are merely based on speculation.

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) is currently undergoing a Phase II trial, and BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers has completed Phase I. In addition, BioLineRx has eight 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, the content of which does not form a part of this press release.

Various statements in this release concerning BioLineRx's future expectations 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: risks and uncertainties associated with market conditions and the satisfaction of customary closing conditions related to the proposed offering. 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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