



BioLineRx Announces Results from Interim Analysis of Phase II/III CLARITY Trial of BL-1020 for Schizophrenia

March 20, 2013 1:00 PM IST

Management call scheduled for Wednesday, March 20th, at 11:00 a.m. EDT

JERUSALEM--(BUSINESS WIRE)--Mar. 20, 2013-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, today announced that results from a pre-planned interim analysis of the Phase II/III CLARITY trial of BL-1020, a first in class, orally available, GABA-enhanced antipsychotic for the treatment of schizophrenia, indicate that the trial would not meet the pre-specified primary efficacy endpoint. After conferring with the study's independent Data Monitoring Committee (DMC), the Company has decided to discontinue the CLARITY study. No additional patients will be enrolled in the trial.

"These disappointing results underscore the difficulty of treating cognition in schizophrenia, which remains an unmet medical need," stated Kinneret Savitsky, PhD, Chief Executive Officer of BioLineRx. "We would like to thank the patients and investigators for their participation and engagement in the study. While we certainly would have preferred to see a positive outcome on this trial, the decision to perform the interim analysis, without waiting until the end of the study, provides us with the opportunity to allocate additional resources to our other projects in order to accelerate their development. This confirms the advantage of our business model, which is based on a broad pipeline with a number of compounds, at different stages of development, and for multiple indications."

As a result of the CLARITY study termination, the Company anticipates that planned research and development expenses will decrease for the remainder of 2013 and part of 2014 by approximately \$6 to \$7 million, thus allowing the Company's current cash reserves of approximately \$28 million to fund its expected operations into 2015. The Company expects to meet a number of significant clinical milestones related to other pipeline assets in the next 12-18 months.

About Phase II/III CLARITY Study Interim Analysis

The interim analysis included data on 230 subjects, of which 168 were evaluable for analysis on the primary (six-week) cognitive endpoint. The analysis indicated no efficacy of BL-1020, in comparison to Risperidone, relative to the cognitive primary and secondary (12-week and 24-week) endpoints. However, in several statistical parameters specified in the statistical analysis plan (SAP), positive trends in cognition were observed. The Company intends to perform a complete analysis of the un-blinded study data on all patients enrolled to date in order to ascertain whether there may be future potential for the product.

Conference Call and Presentation

BioLineRx's management will hold a conference call to discuss the Phase II/III CLARITY interim analysis results for BL-1020 today, March 20, 2013, at 11:00 a.m. EDT. To access the conference call, please dial 1-866-229-7198 from the U.S. or +972-3-918-0691 internationally. The call will also be available via live audio webcast through BioLineRx's website. The corresponding slides will be available via download on the home page of BioLineRx's website, www.biolinerx.com, starting approximately 15 minutes before the conference call.

A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-877-456-0009 from the U.S. or +972-3-925-5944 internationally. The replay will be available through March 23, 2013.

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-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria 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-7040 for treating inflammatory bowel disease (IBD) is currently undergoing a Phase II trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase II study; BL-1021 for neuropathic pain is in Phase I development and BL-1020 for schizophrenia. In addition, BioLineRx has six 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 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 12, 2013. 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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