



BioLineRx's EDP-14, for Treatment of Severe and Persistent Asthma, to Enter the Company's Main Therapeutic Pipeline as BL-9010

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Preclinical data shows that EDP-14 significantly blocks allergic responses

JERUSALEM--(BUSINESS WIRE)--Feb. 28, 2013-- BioLineRx (NASDAQ: BLRX)(TASE: BLRX), a biopharmaceutical development company, announced today that following promising pre-clinical data, EDP-14, for the treatment of severe and persistent asthma, has been added to the Company's main therapeutic pipeline. The project is now named BL-9010. Previously, the project was developed under BioLineRx's Early Development Program.

BL-9010, a novel bi-specific antibody treatment for severe and persistent asthma, targets and links together two immunological modulators - IgE and CD300a. Allergen-bound IgE activates cells involved in allergic responses, such as mast cells, while CD300a inhibits immune responses. Professor Francesca Levi-Schaffer from the Hebrew University of Jerusalem, the inventor of BL-9010, found that CD300a is expressed on mast cells and that linking IgE with CD300a using a bi-specific antibody leads to potent inhibition of allergic reactions characteristic of asthma. In murine models of experimental asthma, BL-9010 significantly blocked allergic responses. Importantly, this could be reproduced in human mast cells, where BL-9010 was shown to inhibit the allergic reaction of these cells in-vitro. The human mast cells were activated by IgE molecules from allergic patients and by specific allergens, mimicking the human disease, while BL-9010 prevented the release of allergy-mediating substances by the cells.

"Asthma is a highly prevalent disease with no satisfactory cure that affects millions of people around the world," said Dr. Kinneret Savitsky, CEO of BioLineRx. "The results of the pre-clinical trials were extremely impressive and convincing, and raise hopes that BL-9010 will be an effective treatment. As a result, the project is now being advanced to our main product pipeline and will be further developed at an accelerated pace. Due to its unique mechanism of action, promising *in-vivo* results and the true unmet medical need, this project, although still in pre-clinical stages of development, is already attracting the interest of potential partners."

BL-9010 was developed to treat severe and persistent asthma patients, but may also potentially treat chronic urticaria as well as additional allergic conditions.

About Asthma

Acute asthma, also known as allergic asthma, is triggered by allergens activating mast cells located beneath the mucous membranes of the lower airways of the respiratory tract. Activation of mast cells triggers release of substances that stimulate the nasal epithelium to produce mucus, as well as the subsequent contraction of smooth muscle within the airway. This contraction of smooth muscle constricts the airway, causing the characteristic asthmatic wheezing. Chronic asthma is not caused by allergens, but rather is the result of inflammation due to repeated episodes of acute asthma. About 90% of children with childhood asthma have allergies, compared with about 50% of adults with asthma. Asthma affects 300 million individuals worldwide, of which 24.5 million are in the U.S. The severe asthma market was estimated at \$1.2 billion in 2011 (based on Xolair sales), and is forecasted to grow to \$1.5 billion by 2016.

About BioLineRx's Early Development Program (EDP)

EDP, a unique program to identify and advance novel and innovative therapeutic research projects, was established by BioLineRx in June 2007. The program seeks to identify and advance such projects from early stages, even before in vivo activity has been demonstrated. In the framework of this program, projects are provided with up to two years of funding, in addition to obtaining professional and scientific support from BioLineRx's development team. The program is principally funded via a \$5 million grant received from the Pan Atlantic Group (Albert Friedberg Family), and now includes 10 research projects.

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, including specifically those related to the development and commercialization of BL-1020, 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 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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