



BioLineRx Announces Successful Completion of Pre-Clinical Development for BL-8020, an Oral, Interferon-Free Treatment for Hepatitis C

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- Phase I/II clinical study expected to commence in Q1 2013 -

JERUSALEM--(BUSINESS WIRE)--Oct. 16, 2012-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that it has successfully completed the pre-clinical development of BL-8020, an orally available, interferon-free treatment for the Hepatitis C virus (HCV), and plans to commence a Phase I/II safety and efficacy study for BL-8020 in Europe during the first quarter of 2013.

Since in-licensing BL-8020 in January 2012, BioLineRx has successfully completed a number of pre-clinical studies with the therapy. The data package is now ready for the regulatory submissions required to begin the clinical phase of development. BioLineRx is currently engaged in the regulatory submission process and expects to receive approval from the regulatory authorities by the end of this year.

BL-8020 is an orally available HCV treatment with a unique mechanism of action, as compared to other currently used anti-HCV agents, which suggests pan-genotypic efficacy and the ability to be combined with other HCV therapeutics as part of an interferon-free regimen. BL-8020's mechanism of action involves the inhibition of HCV-induced autophagy in the host cells. Autophagy is a mechanism by which cells degrade damaged or unnecessary cellular components, including invading viruses. However, HCV has found a way to take advantage of this mechanism in order to replicate inside the cell. By inhibiting this mechanism, BL-8020 reduces the ability of HCV to replicate.

BL-8020's safety and efficacy have been demonstrated in a number of studies. These studies have shown that BL-8020 has a synergistic effect with other anti-HCV agents. This effect on other therapies is likely to increase their potency and reduce the numerous adverse effects often associated with these drugs by enabling utilization of lower dosages. In addition BL-8020 may reduce therapy duration. The use of multiple therapies with different mechanisms is also likely to be beneficial for patients who have developed resistance or do not respond to current treatments and is a common practice in current HCV treatment regimens.

BL-8020 was licensed under a worldwide, exclusive agreement from Genoscience, a French company focused on viral disease therapeutics. It was developed as an anti-viral therapy by Professor Philippe Halfon, Co-Founder and President of Genoscience and a world renowned scientist for his work on HIV (AIDS virus), HPV (human papilloma virus causing cervical cancer) and Hepatitis. In addition, Prof. Halfon is the founder of several biotechnology companies focusing on antiviral drug discovery and development, including ACTgene, Alphabio and Genoscience.

"We are excited that this project has successfully completed the pre-clinical stage," stated Dr. Kinneret Savitsky, CEO of BioLineRx. "The unique characteristics of BL-8020 make it attractive as an adjunct therapy to other oral cocktail therapies, therefore not directly competing in the crowded HCV market of currently approved therapies or those under development. Recent toxicity issues seen with NS5B inhibitors stress the need for additional targets and approaches in HCV treatment. We look forward to entering the clinic with this promising drug at the beginning of next year," Dr. Savitsky added.

"I am very pleased with BioLineRx's accelerated development program for BL-8020," said Prof. Philippe Halfon, Co-Founder and President of Genoscience. "According to the World Health Organization, approximately 3% of the world's population is infected with the Hepatitis C virus. Most infected people develop a chronic infection, making HCV the leading cause for liver transplants in the US. While there have been some recent advancements in the global HCV therapeutics pipeline, there is still a clear need for safe, pan-genotypic therapies, as well as treatments for mutations which may develop resistance to current and future therapies, and for partial and non-responders. Based on the pre-clinical results of BL-8020, its unique mechanism of action and synergistic effect, I believe that this product, especially when combined with other available Hepatitis C drugs, has real potential to meet these future market needs."

About Hepatitis C

Hepatitis C infection is a blood borne infection of the liver caused by the Hepatitis C virus (HCV) which becomes chronic in about 85% of cases. According to a 2011 report from Decision Resources, about 180 million people worldwide are chronically infected with HCV. In addition, HCV infection is the leading cause of liver transplantation and is a risk factor for liver cancer. The global Hepatitis market was estimated at \$6 billion in 2011 and is forecasted to grow to \$20 billion by the end of the decade.

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) has commenced a Phase II trial, and BL-8040 for treating acute myeloid leukemia (AML) has completed Phase I. In addition, BioLineRx has nine 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, including specifically those related to the development and commercialization of BL-8020, 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

KCSA Strategic Communications

Garth Russell / Todd Fromer

1 212-896-1250 / 1 212-896-1215

grussell@kcsa.com / tfromer@kcsa.com

or

BioLineRx

Tsipi Haitovsky

Public Relations

+972-52-598-9892

tsipih@netvision.net.il