



## BioLineRx Enrolls First Patient in Phase I/II Clinical Trial for BL-8020, an Oral, Interferon-Free Treatment for Hepatitis C

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### **- Interim results are expected by the end of 2013 -**

JERUSALEM--(BUSINESS WIRE)--Apr. 29, 2013-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today enrollment of the first patient in a Phase I/II trial for BL-8020, an orally available, interferon-free treatment for the Hepatitis C virus (HCV). The patient was enrolled at the Hôpital Cochin in Paris, France.

The study is an open-label trial to evaluate the efficacy, safety and tolerability of BL-8020 in patients infected with HCV. It will be conducted at two clinical sites in France and will include up to 32 HCV-infected patients of any genotype who have previously failed or relapsed following treatment with the standard-of-care. BL-8020 is a proprietary fixed-dose combination treatment composed of Ribavirin and Hydroxychloroquine (HCQ), which results in an improved version of Ribavirin. The primary endpoint of the study is to evaluate the effect of a 16-week combination therapy with Ribavirin and HCQ. The study is specifically designed to allow intra-subject analysis, in order to determine the extent to which HCQ enhances Ribavirin's antiviral activity.

BL-8020 is an orally available HCV treatment with a unique mechanism of action that targets the host cell, and thus differs from other currently used anti-HCV agents. This 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, and is known to be used by HCV during viral replication. BL-8020 inhibits the autophagy mechanism and thus reduces the ability of HCV to replicate in the human cell.

BL-8020's safety and efficacy have been demonstrated in a number of pre-clinical 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. The use of multiple therapies with different modes of action 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.

"We are very pleased with the initiation of a clinical trial for our first anti-HCV agent, BL-8020. HCV induces a chronic infection in over one-half of individuals infected and, depending on the virus genotype, as few as 60% completely recover. In addition, current standard-of-care treatment options are lengthy and not well tolerated," stated Dr. Kinneret Savitsky, CEO of BioLineRx. "Accordingly, there is a clear need for new drugs that can increase the effectiveness of existing treatments, especially in patients who have already undergone treatment, but have previously failed to respond or relapsed. In this respect, this study would be a first step in establishing in patients the synergistic potential of BL-8020 in combination with other HCV treatments. Based on its pre-clinical results, unique mechanism of action and synergistic effect with other anti-HCV compounds, we are very hopeful that BL-8020 will indeed enhance the activity of other available Hepatitis C treatments, thereby improving Hepatitis C care. We look forward to the partial results from the Phase I/II trial expected towards the end of 2013."

"We are also excited about the initiation of the Phase I/II clinical trial with BL-8020," stated Professor Stanislas Pol from Hôpital Cochin in Paris, the lead principal investigator in the study. "Preclinical results in our ex-vivo model of infected human liver slices showed a time and dose-dependent inhibitory effect on HCV replication and infectivity. We hope that this drug, especially when combined with other available Hepatitis C drugs, will improve the treatment outcome of previously non-responsive patients," said Professor Pol.

### **About BL-8020**

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, HPV (human papilloma virus causing cervical cancer) and Hepatitis.

### **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 seven 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) has completed a Phase IIa 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; BL-8020 for hepatitis C (HCV) is commencing a Phase I/II study; and BL-1020 for schizophrenia. In addition, BioLineRx has five 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](http://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-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 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.*

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