BioLineRx Announces Receipt of a Notice of Allowance from USPTO for Patent on Use of BL-8020, an Oral, Interferon-Free Treatment for Hepatitis C

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- Patent valid until at least 2031 -

JERUSALEM, Sept. 17, 2013 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ:BLRX) (TASE:BLRX), a biopharmaceutical development company, announced today that a Notice of Allowance has been issued by the United States Patent and Trademark Office (USPTO) for BL-8020, an orally available, interferon-free treatment for hepatitis C. The patent covers the use of BL-8020 for treating HCV-infected patients non-responsive to an anti-HCV therapy (patients who failed to achieve a sustained virologic response following treatment). The patent will be valid until at least 2031.

(Logo: http://photos.prnewswire.com/prnh/20130730/630769)

"We are very pleased to have received a Notice of Allowance from the USPTO for the BL-8020 patent. This is an important milestone in the development of this promising drug candidate," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "HCV induces a chronic infection in more than half of individuals infected with the disease and, depending on the virus genotype, as few as 60% completely recover. In addition, current standard-of-care treatments are lengthy and not well tolerated. As a result, there is a clear need for therapeutics that can increase the effectiveness of existing treatments, especially in patients who have already undergone treatment, but have failed to respond or have relapsed. 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 enhance the effectiveness of other available hepatitis C treatments, thereby significantly improving hepatitis C care. We look forward to the partial results from the Phase 1/2 trial expected towards the beginning of 2014."

BioLineRx is currently conducting a Phase 1/2, open-label study at two sites in France to evaluate the efficacy, safety and tolerability of BL-8020 in patients infected with HCV. The study 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 oral, fixed-dose combination treatment composed of Ribavirin and Hydroxychloroquine (HCQ). 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.

About BL-8020
BL-8020 is a proprietary fixed-dose combination treatment composed of Ribavirin and Hydroxychloroquine (HCQ). Efficacy results in replicon assays, as well as in ex-vivo infected human liver samples, showed a time and dose-dependent inhibitory effect of BL-8020 on HCV replication and infectivity. In addition, a synergistic effect with other anti-HCV agents was observed in these models. This effect on other therapies is likely to increase their potency and reduce the numerous adverse effects often associated with these drugs by reducing their effective doses. BL-8020 targets the infected host cells and inhibits HCV induced autophagy in the host. This unique mechanism of action differentiates BL-8020 from other currently used anti-HCV agents in its potential pan genotypic activity and high genetic barrier to resistance (low susceptibility for drug-resistant mutations to be developed by the virus). 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 dedicated to building a portfolio of products for unmet medical needs, as well as those with advantages over currently available therapies. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in late 2013; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which is expected to commence a Phase 1/2 study in late 2013.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

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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