



BioLineRx Announces CE-Mark Registration Trial Submission for Novel Treatment for Removal of Skin Lesions

July 29, 2013

- Study expected to begin in Q4 2013 -

- Results expected in mid-2014 -

JERUSALEM--(BUSINESS WIRE)--Jul. 29, 2013-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that it has filed the necessary regulatory submissions to commence a pivotal, CE-Mark registration trial for BL-5010P - for the non-surgical removal of skin lesions - with the German Federal Institute for Drugs and Medical Devices (BfArM), as well as with the relevant ethics committees.

The pivotal study is a single-arm, open-label, bridging study of BL-5010P, a pen-like applicator containing BL-5010, a novel aqueous solution. The primary objective of the study is to assess the efficacy of a single application of BL-5010P for the removal of seborrheic keratosis (SK) lesions. Secondary objectives include safety and tolerability assessments of the cosmetic outcomes as evaluated by both patients and investigators, and the ability to preserve the treated SK lesions for histopathological diagnosis. Up to 20 patients are expected to be enrolled at three leading sites in Germany. BioLineRx is collaborating with the Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Project Group Translational Medicine & Pharmacology TMP ("Fraunhofer Institute") regarding the operational and regulatory aspects of the trial.

"The novel BL-5010 formulation has already demonstrated outstanding results in the treatment of benign skin lesions in a 60-patient clinical trial conducted in Germany and the Netherlands," stated Kinneret Savitsky, Ph.D., Chief Executive Officer of BioLineRx. "In that trial, a single application of BL-5010 achieved lesion removal in 96.7% of the cases. Now, we intend to perform a pivotal bridging study on the final product, known as BL-5010P, which comprises both the novel formulation and a unique, state-of-the-art, pen-like applicator. Success in this study should enable us to immediately apply for CE-Mark registration of the product, which could be ready for the European market by the second half of 2014. Future development plans include expansion to additional therapeutic indications, including actinic keratosis, a pre-cancerous skin condition. In parallel to completing preparations for the study, we are also continuing to hold discussions with potential partners," concluded Dr. Savitsky.

"We were encouraged by the promising data of BioLineRx's novel formulation for the non-surgical removal of skin lesions. The Fraunhofer Institute is delighted to enter into this close collaboration with BioLineRx, as our Division for Clinical Research maintains responsibility for all regulatory processes at the German sites," stated Dr. Frank Behrens, Head of Clinical Research at Fraunhofer-IME-TMP in Frankfurt/Main.

About BL-5010 and BL-5010P

BL-5010 is a novel aqueous formulation composed of approved components for the non-surgical removal of benign skin lesions such as seborrheic keratosis. BL-5010 offers an alternative to painful, invasive and expensive removal treatments including surgery, cryotherapy or laser treatment. Because the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia or bandaging. The formulation is applied topically to the lesion for a few seconds and causes the lesion to gradually dry out and fall off within one to four weeks. BL-5010P is a disposable, non-invasive, pen-like applicator containing the BL-5010 solution. Both BL-5010 and BL-5010P have received confirmation in Europe for the regulatory pathway classification as a medical device Class IIa.

A Phase 1/2 pilot study, performed on 60 patients with SK, demonstrated that a single, topical application of BL-5010 was effective in 96.7% of cases for removal of the target lesion within 30 days. In addition, the treatment was well-tolerated and no persistent irreversible adverse effects were observed at the treated site. Furthermore, cosmetic outcomes were highly rated by both patients and investigators. BL-5010 was invented by Prof. Pinchas Burstein and is being developed under a worldwide exclusive license from Innovative Pharmaceutical Concepts, Ltd. During the course of developing BL-5010, Prof. Burstein accumulated additional data on the product showing that BL-5010 can be relevant for other types of skin lesions as well.

About Seborrheic Keratosis and Actinic Keratosis

Seborrheic keratosis (SK) is a very common, benign skin lesion that commonly appears during adult life. Patients with SK often request treatment due to symptoms of itching and irritation, or due to cosmetic reasons. Such lesions can be painful and also tend to become injured and sometimes bleed and/or become infected. Actinic keratosis (AK) is a pre-cancerous skin condition that appears as a dry, scaly, sometimes hyperkeratotic lesion caused by prolonged and repeated sun exposure. AK is the most common pre-cancerous skin lesion and treatment of AK is the most frequent dermatologic procedure performed in out-patient clinics. At present, skin lesions that are not suspected to be malignant are treated by methods such as cryotherapy, laser therapy, or electro-cauterization. Such treatments often lead to complications that include pain, bleeding and discharge, as well as infection, blistering and hematoma. These complications commonly necessitate the application of localized antibiotics as well as bandaging; are liable to cause further discomfort to the individual treated; and the healing process is liable to be slow and prolonged, and may lead to scarring. Furthermore, cryotherapy, laser therapy, and electro-cauterization destroy the treated skin region, making histopathological diagnosis of the skin lesions impossible. The total AK and SK market is estimated at over \$500 million worldwide.

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, and 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 1/2 study; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers has commenced a Phase 2 study; BL-7040 for treating inflammatory bowel disease (IBD) has completed a Phase 2a trial; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; BL-1021 for neuropathic pain is in Phase 1 development; 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 3) 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-5010, 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

KCSA Strategic Communications

Garth Russell / Todd Fromer

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

grussell@kcsa.com / tfromer@kcsa.com

or

BioLineRx

Tsipi Haitovsky

Public Relations

+972-3-6240871

tsipih@netvision.net.il