BioLineRx Announces Receipt of Notice of Allowance from USPTO for Patent Covering BL-5010, a Novel Treatment for Removal of Skin Lesions

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JERUSALEM, Oct. 7, 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 a patent application claiming the composition of BL-5010, a novel composition for the non-surgical removal of skin lesions. This patent, when issued, will be valid until 2022, with corresponding patents already granted in Europe and Israel. A second patent application in respect of the product is pending worldwide. Patents to be issued in the future based on this application will be valid until 2033.

(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-5010 patent," stated Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx. "The novel BL-5010 formulation has already demonstrated outstanding results in a 60-patient clinical trial for seborrheic keratosis, in which a single application of BL-5010 achieved lesion removal in 96.7% of the cases, along with good to excellent cosmetic outcomes. We are now in final preparations for a pivotal CE-mark registration trial on the final product, known as BL-5010P, expected to begin by the end of this year. 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 end of 2014. Our future development plans for this product include expansion to additional therapeutic indications, including actinic keratosis, a pre-cancerous skin condition. In parallel, we are also currently engaged in meaningful discussions with potential partners."

About BL-5010 and BL-5010P
BL-5010 is a novel aqueous formulation composed of approved components for the non-surgical removal of benign and pre-cancerous skin lesions, such as seborrheic keratosis (SK) and actinic keratosis (AK). 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 Class IIa medical device.

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 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-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.

Contact:
KCSA Strategic Communications
Garth Russell / Todd Fromer
+1-212-896-1250 / +1-212-896-1215
grussell@kcsa.com / tfromer@kcsa.com

or

Tsipi Haitovsky
Public Relations
+972-3-6240871
tsipih@netvision.net.il

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