



BioLineRx Receives Approval to Commence Pivotal Trial for Novel Skin Lesion Treatment

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- CE Mark registration trial for BL-5010P expected to begin H1 2014; results expected H2 2014 -

JERUSALEM, Jan. 21, 2014 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that it has received approval from the German Federal Institute for Drugs and Medical Devices (BfArM) to commence a pivotal, CE Mark registration trial for BL-5010P, for the non-surgical removal of benign skin lesions.

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

BL-5010P is a disposable, pen-like applicator containing BL-5010, a novel aqueous solution, which is an alternative to painful, invasive and expensive removal treatments such as cryotherapy, laser treatment or surgery. The primary objective of the single-arm, open-label, pivotal bridging study is to assess the efficacy of a single application of BL-5010 in the removal of seborrheic keratosis (SK) lesions. BioLineRx expects to enroll up to 20 patients at up to three leading sites in Germany. The primary study endpoint is the complete lesion removal rate at Days 30, 90 and 180 after treatment. Secondary objectives include safety and tolerability, assessment of cosmetic outcomes by both patients and investigators, and the ability to preserve the treated SK lesions for histopathological diagnosis, which is a key differentiator for BL-5010P. The upcoming pivotal study will be performed using the final product, known as BL-5010P, which comprises both the novel formulation and the unique, state-of-the-art applicator.

"We are very pleased to have received approval from the German authorities to commence a pivotal bridging study for BL-5010P. This important approval reaffirms that BL-5010P will be developed and regulated in Europe as a medical device, meaning that success in this study should enable us to apply for CE Marking immediately, and potentially introduce BL-5010P to the European market in 2015. We also expect to file for approval in other selected markets, including Australia, immediately following receipt of the CE Mark," stated Kinneret Savitsky, Ph.D., Chief Executive Officer of BioLineRx. "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, where a single application achieved lesion removal in 97% of cases. Future development plans include expansion to additional therapeutic indications, including actinic keratosis, a pre-cancerous skin condition, viral warts and skin tags. In parallel to completing preparations for the study, we continue to hold discussions with potential partners," concluded Dr. Savitsky.

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 cryotherapy, laser treatment and surgery. 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 2a.

A Phase 1/2 pilot study, performed on 60 patients with SK, demonstrated that a single, topical application of BL-5010 was effective in 97% 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.

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, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. 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 early 2014; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; and BL-7010 for celiac disease, which recently commenced a Phase 1/2 study.

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.

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