



BioLineRx In-Licenses Novel Compound for Treatment of Neuropathic Pain

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BL-1110 was shown in preclinical studies to enhance analgesic effect of morphine while reducing negative side effects

BL-1110 may also be developed for scleroderma

JERUSALEM--(BUSINESS WIRE)--Jun. 23, 2014-- BioLineRx Ltd. (NASDAQ: BLRX)(TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today it has in-licensed BL-1110, a novel compound for the treatment of neuropathic pain. BL-1110 may also be developed for the treatment of scleroderma, an autoimmune disease characterized by a hardening and tightening of the skin and connective tissues. The compound, which had been previously developed as part of BioLineRx's Early Development Program under the name EDP-34, was in-licensed from the University of Colorado.

Neuropathic pain is caused by damage or diseases affecting the nervous system, and usually does not respond well to regular painkillers. One of the most potent drugs for the treatment of neuropathic pain is morphine; however, its efficacy is often significantly limited due to the body's development of tolerance to the drug, as well as its severe side effects. Morphine can create neuroinflammation in the central nervous system, which has been linked to the suppression of morphine analgesia, as well as the enhancement of morphine-induced tolerance, dependence and reward associated with drug abuse. Recent studies show part of these neuroinflammatory effects are triggered by the interaction of morphine with glial cells, which are highly prevalent in the central nervous system. BL-1110, which was invented by Prof. Linda R. Watkins from the Psychology and Neuroscience Department, and Prof. Hang Hubert Yin from the Chemistry and Biochemistry Department – both from the University of Colorado at Boulder, blocks the interaction of morphine with glial cells, thereby enhancing the analgesic effect of morphine, and reducing concurrent adverse effects and inflammatory processes.

BL-1110 is a small molecule that targets the critical TLR4/MD-2 complex formation, thus preventing the binding of morphine to the TLR4 receptor in glial cells. BL-1110 is administered orally, together with morphine or other opioids. In preclinical studies in rats, BL-1110 was shown to enhance the effects of morphine. Furthermore, the studies show the drug penetrates the blood-brain barrier and reaches the central nervous system with high efficiency, that it is safe for use and that it does not induce adverse effects at doses that are much higher than the effective dose.

"BL-1110 works through a novel mechanism-of-action, based on our recent discovery that opioids, such as morphine, cause the activation of glial cells. This glial activation results in the release of pro-inflammatory factors, which suppress the desired opioid-induced neuronal analgesic effect, thereby reducing the efficacy of the opioid. Furthermore, evidence suggests that glial activation contributes to the development of opioid tolerance, dependence and abuse," explained Prof. Hang Hubert Yin. "We therefore have high hopes that BL-1110 will be a valuable companion to opioid therapies, enhancing their efficacy and reducing their negative side effects."

"Neuropathic pain is a major health problem affecting the quality of life of millions of people around the globe on a daily basis. Despite its widespread occurrence, it is notoriously difficult to treat. Opioids, such as morphine, are a potent option for the treatment of neuropathic pain, but they are generally not used as a first-line treatment due to the considerable risk of adverse side effects, tolerance and dependence.

BL-1110 offers the possibility of mitigating morphine tolerance and side effects while enhancing the analgesic effect. This drug could offer a real breakthrough for the treatment of this challenging and persistent pathology. We are therefore very pleased to in-license this drug and continue its development," said Dr. Kinneret Savitsky, CEO of BioLineRx.

About Neuropathic Pain

Neuropathic pain develops as a result of damage to, or dysfunction of, the nervous system and is often a chronic condition. The causes of neuropathic pain can include shingles, diabetes and cancer, but in many cases the underlying pathology is not completely understood. Neuropathic pain does not usually respond to regular pain killers, and can be very difficult to treat; only approximately 50% of patients achieve even partial relief. Annual sales of prescription drugs for neuropathic pain exceed \$6 billion in the seven major markets.

About BL-1110

BL-1110, developed by BioLineRx under its Early Development Program and previously known as EDP 34, is an orally-administered small molecule designed to block the binding of morphine to the toll-like receptor-4 (TLR4) on glial cells. Research shows that besides the activity of opioids on opioid receptors in the neurons, opioids cause activation of glial cells via the TLR4 signaling pathway, which activation results in the release of cytokines and other pro-inflammatory factors that suppress the desired opioid-induced neuronal analgesic effect, thereby reducing the efficacy of the opioid. Furthermore, evidence suggests that glial activation by opioids contributes to the negative side effects of opioid therapy, such as tolerance, dependence and reward associated with drug abuse. BL-1110 prevents morphine- binding to TLR4 receptors on glial cells, resulting in an enhanced analgesic effect and reduced side effects. BL-1110 was invented by Prof. Linda R. Watkins and Prof. Hang Hubert Yin and was in-licensed by BioLineRx from the University of Colorado.

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 Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial; 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 is in the midst of 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-1110, 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 17, 2014. 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 Ltd.

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