BIOLINERX

BioLineRx's Novel Treatment for Non-Surgical Removal of Skin Lesions Receives CE Mark Approval

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TEL AVIV, Israel, April 4, 2016 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ/TASE: BLRX) announced today that its partner, Omega Pharma, now part of Perrigo, has received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of skin lesions. The product's commercial launch by Omega Pharma is expected by mid-2016. Subject to the terms of the licensing agreement with Omega Pharma, BioLineRx plans to provide updates at a later stage regarding the commercial potential of the product and its contribution to the Company's ongoing business.

BL-5010 is a novel product offering an alternative to painful, invasive and expensive skin lesion 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 product has completed clinical studies for the removal of seborrheic keratosis and other skin lesions with excellent efficacy and cosmetic results, and has received confirmation in Europe for the regulatory pathway classification as a Class 2a medical device. BL-5010 was licensed by BioLineRx from Innovative Pharmaceutical Concepts (IPC) Inc.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated: "We are very pleased with the CE mark approval for BL-5010, which is the final step necessary before the product's launch as an OTC treatment in Europe, expected over the next few months. In particular, we would like to thank Omega Pharma for their efficient and professional development of this novel product, and hope this regulatory approval will also expedite the potential expansion of the product to other markets as well as to additional indications."

"We in-licensed BL-5010 as a pre-clinical asset, completed all the necessary pre-clinical and clinical studies, successfully changed the development pathway in Europe from a drug to device, developed a new and unique applicator for the product, and extended the product's patent life by many years. While our clinical and business focus remains on oncology and immunology, BL-5010 is an excellent example of our ability to create value from our non-core products as well, and to successfully bridge the gap between pre-clinical and advanced clinical development stages," concluded Dr. Savitsky.

In December 2014, BL-5010 was out-licensed to Omega Pharma for OTC indications in the territory of Europe, Australia and additional selected countries. BioLineRx retains the OTC rights to BL-5010 in the U.S. and the rest of the world, as well as the global rights to non-OTC indications.

About BioLineRx

BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israelisourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2 study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

For additional information on BioLineRx, please visit the Company's website at http://www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on Eacebook, Twitter, and LinkedIn.

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 10, 2016. 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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