# BioLineRx Announces European Confirmation of Medical Device Regulatory Pathway for BL-5010, for Non-surgical Removal of Skin Lesions

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**Hebrew Version**

**Jerusalem**, **Israel, September 15, 2011** - BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical development company, announced today that BL-5010, for the non-surgical removal of benign skin lesions, has received European confirmation from the British Standards Institution Notified Body (BSI) in the UK, of the regulatory pathway classification as a medical device Class IIa. This considerably reduces the time and resources required for marketing authorization for the product in comparison to the drug approval process.

BL-5010 is a novel formulation for the non-surgical removal of benign skin lesions. In December 2010, BL-5010 completed a Phase I/II clinical trial in which it demonstrated efficacy in complete removal of benign skin lesions and safety.

Kinneret Savitsky, Ph.D., BioLineRx's CEO, stated, "Receiving confirmation of the medical device regulatory pathway, as opposed to the drug approval pathway, is a considerable achievement which significantly shortens the time needed to bring BL-5010 to market. Since announcing the promising results of the Phase I/II clinical trial in December 2010, we have invested considerable efforts in evaluating the appropriate regulatory and development path for this product and we are very pleased with the outcome of these efforts".

**About BL-5010**
BL-5010 is a novel formulation for the non-surgical removal of benign skin lesions. 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 does not require anesthesia or bandaging.

BL-5010 is applied topically on the lesion for a few minutes and causes the lesion to gradually dry out and be shed from the skin within 1-3 weeks.
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**About BioLineRx**
BioLineRx Ltd. 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 five clinical stage candidates: BL-1020 for schizophrenia is in Phase II/III clinical trials; BL-1040 for treatment of patients following a myocardial infarction has completed a Phase I/II study and has been out-licensed to Ikaria Inc. for a total deal value of $282.5 million, in addition to sales royalties; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I trials; and BL-7040 for treating Inflammatory Bowel Disease (IBD) has completed Phase I. In addition, BioLineRx has nine products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, oncology, 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 III) and commercialization. For more information on BioLineRx, please visit www.biolinerx.com.

*The estimates and judgments with respect to the projects included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates may not be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.*

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