



## BioLineRx Signs Exclusive License Agreement with Yissum for Oral Phase II Ready Treatment BL-7040 for Inflammatory Bowel Disease

June 27, 2011

**Jerusalem, June 27, 2011** - BioLineRx (TASE:BLRX), a biopharmaceutical drug development company, and Yissum Research Development Company Ltd., the Technology Transfer Company of the Hebrew University of Jerusalem, announced today that they have signed a worldwide, exclusive license agreement for BioLineRx to develop and commercialize BL-7040, an orally available Phase II ready molecule for treating Inflammatory Bowel Disease (IBD) and other inflammatory diseases.

BL-7040 has dual activity on both the nervous and immune systems, rendering it highly suitable for treating both neurological diseases and immune system related conditions such as inflammatory or autoimmune diseases. It was invented by Professor Hermona Soreq, from the Alexander Silberman Institute of Life Sciences, Faculty of Science and the Edmond and Lily Safra Center of Brain Sciences at the Hebrew University of Jerusalem. Prof. Soreq is a pioneer in molecular biology research responsible for the development of RNA-targeted oligonucleotide drugs for mammalian stress reactions which increase the risk of chronic diseases such as muscle fatigue, inflammation and neurodegeneration.

BL-7040 was previously developed for Myasthenia Gravis (MG), a neuromuscular disease, where it showed a high level of efficacy in Phase Ib and IIa clinical trials. However, after discovering a new mechanism of action for the drug, BioLineRx is designating BL-7040 for IBD and other inflammatory diseases with a much wider market.

"We are excited to add BL-7040 to our pipeline. It has already demonstrated safety as well as its pharmacokinetic profile in earlier clinical trials, so we expect an accelerated development program as we plan to begin Phase II clinical trials for the treatment of IBD," stated Dr. Kinneret Savitsky, CEO of BioLineRx. "With this new addition, we now have five clinical-stage therapeutic products in our pipeline, including three in mid-stage or pivotal trials. BL-1020 for the treatment of schizophrenia is about to begin a Phase II/III clinical trial; BL-1040 for treating patients following a myocardial infarction is about to begin two pivotal trials; BL-5010 for non-surgical removal of skin lesions has successfully completed a Phase I/II study, and BL-1021 for neuropathic pain is currently in Phase I studies."

"We are very pleased to once again collaborate with BioLineRx, which has the drug development expertise to further develop this therapy," said Yaacov Michlin, CEO of Yissum. "BL-7040 addresses the very mechanism causing inflammatory diseases and therefore has the potential to offer a breakthrough in the treatment of IBD and make a positive impact on millions of lives."

Prof. Hermona Soreq, added, "This new drug acts to suppress inflammatory responses by directly activating an anti-inflammatory agent, namely TLR-9, an innate immune system protein, and concomitantly by increasing the activity of the cholinergic, anti-inflammatory, pathway. This dual action renders BL-7040 unique in the field of anti-inflammatory drugs, and presents a new and improved treatment for inflammatory disease."

BL-7040 possesses anti-inflammatory properties, as shown in preclinical studies. In these studies, BL-7040 led to amelioration of parameters associated with inflammatory bowel disease, an inflammatory gastrointestinal tract disorder. The efficacy of BL-7040 in these studies was shown to be highly significant and comparable to that of dexamethasone, a steroid used routinely for IBD that has multiple side effects.

### **About Inflammatory Bowel Disease (IBD)**

IBD is a chronic inflammatory gastrointestinal disease characterized by chronic abdominal pain, discomfort, bloating and alteration of bowel habits. Approximately 1 in 500 people worldwide suffer from IBD. The condition has few specific treatment options available. Sales of existing drugs are estimated at \$1.8 billion annually. However, current treatment options do not fully address patients' needs.

### **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 has completed a Phase IIb study; BL-1040, for treatment of patients following a myocardial infarction has completed a Phase I/II study and has been out-licensed to Icaria 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 development 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](http://www.biolineRx.com).

### **About Yissum**

Yissum Research Development Company of the Hebrew University of Jerusalem Ltd. was founded in 1964 to protect and commercialize the Hebrew University's intellectual property. Ranked among the top technology transfer companies in the world, Yissum has registered over 7,000 patents covering 2,023 inventions; has licensed out 530 technologies and has spun-off 72 companies. Products that are based on Hebrew University technologies and were commercialized by Yissum generate today over \$2 billion in annual sales. Yissum's business partners span the globe and include companies such as Syngenta, Vilmorin, Monsanto, Novartis, Johnson & Johnson, Roche, Merck, Teva, Google, Adobe, Phillips and many more. For further information please visit: [www.yissum.co.il](http://www.yissum.co.il).

### **Forward-Looking Statements**

*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, including clinical trial*

*commencement dates, 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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