



## BioLineRx's Treatment for Type 1 Diabetes Effective in Preclinical Trials

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*- Results of experiments with BL-9020, a new antibody treatment, published in PLoS One -*

JERUSALEM--(BUSINESS WIRE)--Mar. 11, 2015-- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today positive pre-clinical results for BL-9020, a novel monoclonal antibody for the treatment of Type 1 diabetes. The results were published on-line in [PLoS One](#).

BL-9020 is a novel monoclonal antibody treatment designed to prevent immune-mediated destruction of insulin-producing beta cells in the pancreas. It was developed to treat Type 1 diabetes in early stage patients, during what is known as the "honeymoon period," where the pancreatic beta cells have not been completely destroyed and continue to secrete insulin. BL-9020 targets NKp46, a unique target that is involved in the innate response against the pancreas. Pre-clinical studies in mouse models of Type 1 diabetes suggest that BL-9020 can inhibit beta cell death, thus preventing full maturation of the disease. This effect could significantly delay, and potentially prevent, the need for chronic insulin use by Type 1 diabetes patients, as well as provide a potential benefit in minimizing diabetes-related complications.

The new set of experiments shows that BL-9020 led to decreased levels of its target, NKp46, on murine NK cells, and specifically reduces the cytotoxic activity mediated by NKp46 in these cells. Consequently, BL-9020 significantly delayed the onset of diabetes and lowered the incidence of Type 1 diabetes in two different mouse models of diabetes. After a single treatment of BL-9020, hyperglycemia was significantly less severe. Moreover, following a repeated long-term treatment regimen of pre-diabetic mice, 70% of mice treated with BL-9020 remained diabetes-free throughout the experiment (25 weeks), compared to only 30% of control-treated mice.

Dr. Kinneret Savitsky, CEO of BioLineRx, stated, "We are greatly encouraged by these pre-clinical studies, showing that BL-9020 is able to delay the development of Type 1 diabetes in pre-diabetic mice. Type 1 diabetes is a highly prevalent autoimmune disease affecting millions around the world. Currently there is no cure for the disease, and patients with diabetes need to administer insulin on a daily basis throughout their lifetime. Many patients experience a "honeymoon period" following diagnosis which may last up to a year and can offer an opportunity for disease modifying therapies. Inhibiting the innate immune system, which has shown involvement in the destruction of the pancreas, is a novel approach for such treatment. In light of these promising pre-clinical results, we hope that BL-9020 will eventually be able to improve the quality of life for millions of children diagnosed with type 1 diabetes."

As previously disclosed, in January 2014, BioLineRx entered into a collaboration agreement with JHL Biotech to collaborate in the development and commercialization of BL-9020. Pursuant to the collaboration agreement, JHL Biotech is responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and BioLineRx is responsible for all pre-clinical development of BL-9020. Responsibility for clinical development of the product will be shared by the parties on a regional basis.

### **About BL-9020**

BL-9020 is a first-in-class, monoclonal antibody that targets the Natural Killer (NK) receptor NKp46, which has been linked to Type 1 diabetes. Studies have shown that Natural Killer cells belonging to the innate immune system have a key role in the damage to pancreatic cells and, as a consequence, in the development of Type 1 diabetes. Professor Ofer Mandelboim from the Hebrew University of Jerusalem and Professor Angel Porgador from Ben-Gurion University, the inventors of BL-9020, together with Professor Yaakov Naparstek and Dr. Chamutal Gur from Hadassah Medical Center in Jerusalem, found that the NKp46 receptor specifically recognizes pancreatic beta cells, leading to their destruction. These findings demonstrate the importance of the NKp46 receptor in diabetes development and emphasize the therapeutic potential of an anti-NKp46 monoclonal antibody as a new treatment modality for Type 1 diabetes. The inhibition of the NK cell receptor, which specifically targets the pancreas, is a novel mechanism with potential to modify the course of the disease.

### **About Type 1 Diabetes**

Type 1 diabetes, which usually appears in children and adolescents, results from auto-immune destruction of the pancreatic beta cells producing insulin. This leads to a pathological, high level of sugar in the blood and urine. This hyperglycemia leads to high morbidity and mortality rates. Treatment of Type 1 diabetes is currently limited to lifetime administration of insulin by injection. The disease affects over 30 million people worldwide, and in 2012 the Type 1 diabetes market was estimated at over \$3.5 billion.

### **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 scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

For more information on BioLineRx, please visit [www.biolinerx.com](http://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-9020, 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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