BIOLINERX

BioLineRx and JHL Biotech to Collaborate on Type 1 Diabetes Antibody Treatment

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- JHL Biotech to develop and commercialize BL-9020 in China and additional Southeast Asia countries -

JERUSALEM and HSINCHU, Taiwan, Jan. 8, 2014 /PRNewswire/ -- BioLineRx (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, and JHL Biotech, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines, announced today that they have entered into an agreement to collaborate in the development and commercialization of BL-9020, a novel monoclonal antibody for the treatment of Type 1 diabetes.

(Logo: http://photos.prnewswire.com/prnh/20130730/630769)

Pursuant to the collaboration agreement, JHL Biotech will be responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and BioLineRx will be responsible for all pre-clinical development of BL-9020. Responsibility for clinical development of BL-9020 will be shared by the parties on a regional basis.

BL-9020 is a novel monoclonal antibody treatment designed to prevent 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. Pre-clinical studies in mouse models of Type 1 diabetes suggest that BL-9020 can preserve surviving cells, 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.

Under the terms of the agreement, JHL Biotech will have global manufacturing rights to BL-9020, along with development and commercialization rights in China and Southeast Asia, and BioLineRx will have development and commercialization rights in the rest of the world. In all development and manufacturing of BL-9020, JHL Biotech will adhere to FDA guidelines and regulations. Each of JHL Biotech and BioLineRx will have rights to all development and regulatory data generated under the agreement in order to commercialize BL-9020 in its respective territory. Each party will also be entitled to single-digit royalties on the sale of BL-9020 in the other party's respective territory.

"We are extremely pleased to partner with JHL Biotech, one of the rising stars of the Chinese biotech industry, with its impressive expertise in the development and manufacturing of biologic products, as well as its existing collaborations with leading global players. We view this as a strategic long-term partnership that we hope will form the basis for additional co-development projects for other biologic therapies," stated Dr. Kinneret Savitsky, CEO of BioLineRx.

"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. Oftentimes, when the disease is diagnosed, patients experience a "honeymoon period" that may last up to a year, during which there are still some insulin producing cells in the pancreas. Based on promising preclinical results, we have high hopes that BL-9020 may slow down or halt progression of the disease at this stage, which could be a significant step towards curing diabetes," added Dr. Savitsky.

Mr. Racho Jordanov, CEO of JHL Biotech, stated, "China is unfortunately experiencing a diabetes epidemic, with approximately 100 million people inflicted and a projection of reaching 150 million by 2035, thus making China one of the largest diabetes markets worldwide. Type 1 diabetes accounts for 5-10% percent of diabetes cases. It is diagnosed mainly during childhood and inflicts patients on a chronic basis for their entire lives. We believe that BioLineRx's novel drug for the prevention of Type 1 diabetes holds great promise for improving the health and welfare of people in China and throughout Southeast Asia."

"Israel is a global center for innovative technologies, and we hope our collaboration with BioLineRx will expand to other products, contributing to our vision of making world-class biopharmaceuticals affordable and accessible to all patients," concluded Mr. Jordanov.

About BL-9020

BL-9020 is a first-in-class, monoclonal antibody which 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 Progador 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 in both animal and human cells. 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 NK cells that are specifically targeted to 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. Treatment of Type 1 diabetes is currently limited to lifetime administration of insulin by injection. The disease affects over 20 million people worldwide, and in 2012 the Type 1 diabetes market was estimated at over \$3.5 billion.

About JHL Biotech

JHL Biotech is an emerging biopharmaceuticals company, founded by a group of biotech veterans and backed by a consortium of top-tier venture capital firms that includes Kleiner Perkins Caufield & Byers, Burrill & Company, China Development Investment Bank, and Sequoia Capital, with the mission to develop, manufacture, and commercialize world-class, affordable biologic medicines. JHL Biotech focuses on high-quality, cost-effective bioengineering as well as innovative product development technologies that follow current Good Manufacturing Practices (cGMP). In its first year, JHL Biotech has five biosimilar programs and one new molecular entity in development. JHL plans to submit its first clinical trial and investigational new drug applications in 2014 and expects to be cash flow positive and profitable by 2016.

JHL Biotech has built new headquarters, research, and manufacturing facilities in Taiwan to support all pre-clinical and early clinical biologic development. New facilities are also being built in Wuhan, China to support commercial manufacturing. When completed in early 2015, the Wuhan facility will be the largest single-use cell culture plant in the world.

The two cGMP facilities were designed and built in collaboration with GE Healthcare and utilize the latest in single use bioreactor technology. With this infrastructure, JHL Biotech has the advantage of strong intellectual property protection in Taiwan, the opportunity to serve the local market in China, and the capabilities to provide process development and bioengineering services to global partners.

For more information on JHL Biotech, please visit www.jhlbiotech.com.

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 Ikaria Inc. and is in the midst of a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in early 2014; 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 recently commence a Phase 1/2 study.

For more information on BioLineRx, please visit <u>www.biolinerx.com</u> 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 12, 2013. 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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