

# BioLineRx Announces In-licensing of Novel Treatment for Liver Failure Conditions Under Strategic Collaboration

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Therapeutic compound is second project in-licensed under strategic collaboration with Novartis for screening and development of novel drug candidates

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BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today that it has signed an exclusive, worldwide agreement with BGN Technologies, the Technology Transfer Company of Ben-Gurion University, and Hadasit, the Technology Transfer Company of Hadassah Medical Organization, for the in-licensing of a novel treatment for various liver failure conditions such as end-stage liver disease (ESLD) and for conditions potentially leading to liver failure such as non-alcoholic steatohepatitis (NASH). This novel treatment, to be named BL-1220, is the second project in-licensed under the framework of the Company's strategic collaboration with Novartis Pharma AG for the screening and development of novel drug candidates.

BL-1220 is an orally administered, novel composition of sodium alginate, developed by Professor Smadar Cohen from the Department of Biotechnology Engineering, Ben-Gurion University of the Negev, Israel, and Professor Yaron Ilan, Head of Internal Medicine Department A, Hadassah Medical Center, Jerusalem, Israel. Pre-clinical results obtained in animal models of liver impairment suggest that BL-1220 has strong hepato-protective effects. Collectively, the data demonstrate that BL-1220 is able to restore liver function. This technology could be directed toward rapid regeneration of normal liver in both acute and chronic conditions of liver injury.

Philip Serlin, Chief Financial and Operating Officer of BioLineRx, said, "In August this year, we in-licensed the first compound under our multi-year strategic partnership with Novartis, a novel drug candidate for controlling liver fibrosis through modulation of the immune system. Today, we are pleased to announce the second compound under the Novartis collaboration, also for the treatment of liver pathologies. Both of these projects fit our strategic focus on the immunology space. We continue to work closely with Novartis to identify cutting-edge, novel therapies and we expect to bring additional promising projects to the collaboration by the end of the year."

In December 2014, BioLineRx and Novartis Pharma AG entered into a multi-year strategic collaboration to facilitate development and commercialization of Israeli-sourced drug candidates. Leveraging BioLineRx's close and long-lasting ties with academic institutions, hospitals and biomedical companies in Israel, as well as its proven project screening process and development expertise, Novartis will evaluate projects identified and presented by BioLineRx for co-development and potential future licensing under the collaboration. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept. As part of the agreement, Novartis made an equity investment in BioLineRx of \$10 million.

## About Non-Alcoholic Steatohepatitis and End-Stage Liver Disease

Non-alcoholic steatohepatitis (NASH) is the progressive form of non-alcoholic fatty liver disease (NAFLD), and in many cases the resulting liver scarring is associated with liver cirrhosis. It is estimated that NASH affects 2% to 5% of the global population, and according to the US Association of Liver Disease, of those who will develop NASH, 15%-25% will progress to end stage liver disease (ESLD) and hepatocellular carcinoma (HCC) over 10-20 years. To date, a third of liver transplants and HCC cases are caused by NASH and it is expected to be the principal cause for transplantation by 2020. Currently there are no FDA-approved treatments for NASH, thus new potent therapeutics are an unmet medical need.

### 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 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment, and has recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; 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 Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and has recently signed a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's Atezolizumab in several Phase 1b studies for multiple solid tumor indications and AML.

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

# **About Hadasit**

Hadasit is the Technology Transfer company of the Hadassah Medical Organization in Jerusalem, Israel. The Hadassah Medical Center, established 100 years ago and regarded as one of Israel's primary hospitals, has accumulated a vast amount of knowledge, medical research, dedication and innovation. The combination of practical experience, ability to pinpoint medical needs and cutting-edge research has yielded a huge potential of ideas, innovation and developments in all aspects of medicine, including therapeutics, diagnostics and medical devices.

In order to realize this potential, Hadassah established Hadasit - the business arm which was founded in 1986 as its vehicle for commercialization of medical technologies developed at the hospitals - and has been investing in turning ideas into viable products and services for the benefit of humanity. Hadasit collaborates with leading international companies and research facilities as well as incubators and venture capital groups.

#### **About BGN Technologies**

BGN Technologies is the technology transfer and commercialization company of Ben-Gurion University (BGU) and serves as the link between industry and academic research. BGN assists the university and its faculty to translate their inventions and academic achievements into commercially valuable products by collaborating with established Israeli and global companies as well as with new start-ups established for the development of specific BGU inventions. BGN innovations and commercialization cover diverse fields such as pharmaceuticals, drug delivery, biotechnology, medical devices, information technology, security, electro-optics, nanotechnologies, chemical processes, agro-technology, environment and energy big-data and e-health. For more information, please visit <a href="http://www.bgu.ac.ii/bgn">http://www.bgu.ac.ii/bgn</a>.

Various statements in this release concerning BioLineRx's future expectations 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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