# BIOLINERX

# BioLineRx Announces In-licensing of Liver Fibrosis Project Under Strategic Collaboration

## August 1, 2016

## Novel drug candidate modulates immune system to reduce liver fibrosis in non-alcoholic steatohepatitis

# TEL AVIV, Israel, August 1, 2016 /PRNewswire/ --

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 Hadasit, the Technology Transfer Company of Hadassah Medical Organization, for the in-licensing of a drug candidate for the treatment of liver fibrosis, and in particular, non-alcoholic steatohepatitis (NASH). This drug candidate, to be called BL-1210, is the first project to be in-licensed under the framework of the Company's strategic collaboration with Novartis Pharma AG for the screening and development of novel drug candidates.

The newly in-licensed pre-clinical project, developed by Prof. Rifaat Safadi, Head of the Liver Unit, Department of Medicine at Hadassah Medical Center, Jerusalem, Israel, offers a novel mechanism for controlling liver fibrosis through modulation of the immune system. BioLineRx will address the novel drug target that will modulate the immune system to ultimately reduce the liver fibrogenesis and therefore reduce liver scarring. Limiting the fibrosis process this way will potentially control the disease progression.

"After jointly screening and evaluating a wide range of pre-clinical and clinical therapeutic candidates, we are excited with the selection of this potential treatment for non-alcoholic steatohepatitis to be developed as part of our multi-year partnership with Novartis, especially since there are no approved treatments for this prevalent condition," explained Dr. Kinneret Savitsky, CEO of BioLineRx. "Under the collaboration, Novartis will provide us with valuable professional advice and consultancy throughout the development process. This project fits our strategic focus on the immunology space, since it works through modulation of the immune system. Upon successful completion of the feasibility stage, we plan to advance the project at full steam. We also 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

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 NAFLD or NASH, thus new potent therapeutics for NASH in general and anti-fibrotic in particular is 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, and has recently signed 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®.

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

#### 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.

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 forwardlooking statements unless required by law.

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