



## **Exalenz Bioscience Launches Clinical Study for Breath-Based Detection of Primary Liver Cancer (HCC)**

- More than 750,000 new cases of Hepatocellular Carcinoma (HCC) Diagnosed Globally Each Year -

Modi'in, Israel – June 4, 2015 – Exalenz Bioscience (TASE: EXEN), a leader in developing and marketing non-invasive medical devices for diagnosing and monitoring a range of gastrointestinal and liver diseases, today announced the initiation of a clinical study designed to investigate its BreathID® test to non-invasively detect primary liver cancer, also known as Hepatocellular Carcinoma (HCC).

The 100 patient study, being conducted initially at the 302 Military Hospital of China, with other sites in China expected to be added, will evaluate the efficacy of BreathID for the early detection of HCC, compared to magnetic resonance imaging (MRI). MRI is currently part of the recommended practice guidelines by leading medical organizations including the European Association for the Study of the Liver (EASL) and the American Association for the Study of Liver Diseases (AASLD). Following completion of the study, Exalenz plans to conduct a Pivotal study and submit data to both the U.S. Food and Drug Administration (FDA) and the Chinese Food and Drug Administration (CFDA) in support of marketing approval.

"Our goal in primary liver cancer is to detect and treat it early. Accurately diagnosing liver cancer has been historically difficult, because the disease often has no observable symptoms in its early stages and due to the dearth of non-invasive, efficient diagnostic tools," said Prof. Yongping Yang, M.D., principal investigator of the study. "We are encouraged by the potential of BreathID as a new option for clinicians and patients for detecting liver cancer particularly in markets and institutions where conventional diagnostic technologies are not economically or practically feasible."

The efficacy of the Exalenz breath test for detection of HCC was evaluated in a prior clinical study demonstrating a very high correlation with imaging tests like computed tomography that are currently the standard of care. The company estimates the market value of this test is approximately \$380 million in China alone.

"The Exalenz BreathID test has shown promising early evidence of efficacy as a detection tool for liver cancer patients, offering a non-invasive, convenient and cost-effective alternative to currently available technologies," noted Larry Cohen, CEO of Exalenz Biosciences. "We are

excited to launch this study and are optimistic about the BreathID platform to help clinicians detect liver cancer while reducing the cost burden to the healthcare system.”

This study is part of Exalenz’s growing clinical pipeline of investigational diagnostic applications for serious liver diseases. In May, the Company announced the initiation of a clinical study evaluating the potential of its BreathID® test to diagnose nonalcoholic steatohepatitis (NASH). Exalenz also has an ongoing pivotal study, launched October 2014, investigating BreathID® as a tool to diagnose Clinically Significant Portal Hypertension (CSPH).

**About Exalenz Bioscience:**

Exalenz Bioscience develops and markets diagnostic and monitoring systems that use the exhaled breath to diagnose and help manage GI and liver conditions. The company’s flagship BreathID Hp test detects the presence of the H. pylori bacteria, associated with various illnesses including gastric cancer. Exalenz holds regulatory approvals in Europe the US and Israel for H. pylori detection and is currently in the process of obtaining approvals for additional applications.

**About Primary Liver Cancer, Hepatocellular Carcinoma (HCC):**

HCC is the sixth most common cancer in the world, with more than 750,000 cases diagnosed globally in 2012.<sup>1</sup> and a high prevalence in China and other East Asian countries. Approximately 83 percent of liver cancer cases are diagnosed in developing regions of the world and the age-standardized rate of this cancer is more than six times higher in Eastern Asia compared with Northern European populations.<sup>1</sup>

Contact:

David Carey

Lazar Partners Ltd.

T: (212) 867-1768

[dcarey@lazarpartners.com](mailto:dcarey@lazarpartners.com)

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<sup>1</sup> <http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/liver-cancer-statistics>