Exalenz Bioscience Launches Pivotal Study of World's First Breath-Based Test to Diagnose Clinically Significant Portal Hypertension

Portal hypertension is the most common complication of cirrhosis, accounting for significant morbidity and mortality

.Multinational study to be conducted in Europe and the U.S

Modi'in, Israel – October 21, 2014 -- 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, announced the start of a pivotal study investigating the potential of its BreathID® test as a non-invasive tool to diagnose Clinically Significant Portal Hypertension (CSPH), the most common complication of cirrhosis that accounts for significant morbidity and mortality in patients with advanced liver disease. The multinational study will compare the patient-friendly BreathID test to Hepatic Venous Pressure Gradient (HVPG).

During the 200-patient first stage of the study, leading medical centers in Europe and the United States will recruit patients with chronic liver disease. Data collected during this stage will be used to build the index algorithm to compare the BreathID test with HVPG. During the second stage of the study, expected to start in 2016, investigators will verify the algorithm.

Following completion of the pivotal study, Exalenz plans to submit data to the U.S. Food and Drug Administration (FDA) for PMA approval.

Prof. J. Bosch, Hospital Clinic, University of Barcelona, Spain, a study investigator and world leader in diagnosing and treating portal hypertension, said "I am very impressed with the potential of this unique technology by Exalenz Bioscience that is based on measuring different parameters in the patient's breath. This technology can definitely be a breakthrough in the non-invasive detection of liver diseases."

Hepatic portal vein hypertension is currently diagnosed by measuring HVPG (Hepatic Venous Pressure Gradient), an invasive and expensive test that requires local anesthesia and the use of contrast material that may harm the kidneys, and exposes the patient to radiation. In addition, the test requires a high degree of skill, time and resources that are not available in most medical centers.

Exalenz believes that the BreathID test will be a non-invasive, rapid, safe and significantly less expensive alternative test for this large market, estimated by the company to be approximately $100 million. Since the cost and complexities of currently available modalities to detect CSPH could be limiting the

identification of many patients with this serious condition, Exalenz believes that the availability of a more convenient breath-based test could eventually increase the overall size of the market.

"The start of this pivotal study represents an important milestone in our strategic plan to launch a broad portfolio of liver diagnostics based on our patient-friendly BreathID test," said Larry Cohen, CEO of Exalenz Bioscience. "We believe that the availability of a less-invasive test will enable clinicians to detect CSPH in a greater number of chronic liver disease patients, while helping reduce healthcare costs."

Exalenz plans to launch clinical studies for the diagnosis and monitoring of additional liver indications including NASH (non-alcoholic steateohepatitis), HCC (hepatocellular carcinoma) and ALF (acute liver failure). These will be achieved in part through partnering with companies developing therapies for these diseases.

About Exalenz Bioscience:

Exalenz Bioscience develops and markets diagnostic and monitoring systems that use the 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.

Contact:

David Carey
Lazar Partners Ltd.
T: (212) 867-1768
dcarey@lazarpartners.com