Exalenz Bioscience Launches Additional Clinical Study of Breath-Based Diagnostic Test Addressing the $2 Billion NASH Market Potential

- Nonalcoholic Steatohepatitis is a progressive liver disease associated with increased risk for liver cirrhosis, hepatocellular cancer, metabolic and cardiovascular disease -

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

Modi'in, Israel – May 6, 2015 – Exalenz Bioscience (TASE: EXEN), a leader in developing and marketing of non-invasive medical devices for diagnosing and monitoring a range of gastrointestinal and liver diseases, today announced the initiation of a clinical study evaluating the potential of its BreathID® test to diagnose nonalcoholic steatohepatitis (NASH).

NASH is a progressive liver disease characterized by an accumulation of fat in the liver, inflammation and fibrosis, which can lead to cirrhosis, hepatocellular cancer and liver failure. Currently, a definitive diagnosis of NASH can only be achieved through liver biopsy, which is invasive and introduces potential for sampling errors as well as other interpretation limitations.

The 200-patient multicenter prospective study will investigate the clinical utility of BreathID to diagnose NASH, compared to liver biopsy, standard pathological examinations and blood testing. Renowned hepatologists, Prof. Vlad Ratziu, MD, Universite Pierre et Marie Curie Hospital and head of Hepatology at Hospital La Pitié-Salpêtrière, Paris, France, and Dr. Stephen Harrison, MD, Chief of Hepatology, Division of Gastroenterology and Hepatology, Brooke Army Hospital, San Antonio Military Medical Center, San Antonio, Texas, USA - are leading the study.

"Nonalcoholic fatty liver disease (NAFLD) is a significant cause of chronic liver disease affecting both children and adults and its incidence continues to rapidly expand in the Western world. Cases of NASH, the most serious form of NAFLD, also are increasing," noted Dr. Harrison. "A major challenge for our healthcare system is the lack of accurate, non-invasive tools for diagnosing and monitoring the progression of the disease and the effect of therapies on NASH. The BreathID platform shows promise as a convenient, non-invasive diagnostic technology to assist clinicians in managing patients efficiently and rapidly. The BreathID ideally could determine which patients need to undergo further investigation (e.g. biopsy) and help decide which patients should be treated when therapies become available."

The results of this study will be used to optimize the company's proprietary algorithm for diagnosing and monitoring the progression of NASH and the effect of treatment on the disease. It is expected that the optimized algorithm will then be applied to data collected in larger studies in collaboration with pharmaceutical companies investigating treatments for NASH.

"Diagnosing NASH is of paramount clinical importance as it identifies patients at risk of progression and those in need of pharmacotherapy. However, it has been extremely challenging using traditional non-invasive methods based on serum biomarkers or liver imaging. The current study aims to assess a new, and innovative diagnostic test to fulfill this major unmet clinical need within a comprehensive grading and staging of the disease, said Prof. Ratziu."

A previous multi-center pilot study in the US and Israel led by Arun Sanyal, MD, professor of medicine and chairman, Division of Gastroenterology, at Virginia Commonwealth University Medical Center in Richmond, Virginia showed a high correlation between the results of the BreathID test and liver biopsy, offering a new diagnostic option within the rapidly growing global market, which is estimated to be in excess of $2 billion.

“The start of this study represents a significant regulatory and corporate milestone as we fulfill our mission to become the leading provider of non-invasive diagnostic and monitoring systems for a wide range of gastrointestinal and liver disorders,” said Larry Cohen, CEO of Exalenz Bioscience. “We believe that our novel, non-invasive test will not only help diagnose and monitor patients inexpensively at the point of care, but could also accelerate enrollment in ongoing NASH clinical trials to develop effective therapies to treat this disease. Based on proven track record in penetrating the H. pylori breath testing market into hundreds of medical centers in the U.S., we are optimistic about our ability to extend the reach of the proven BreathID platform to other indications with high unmet clinical needs. This study combined with our ongoing clinical study of using the BreathID for assessing Clinically Significant Portal Hypertension or CSPH has the potential of positioning Exalenz to be the leading provider of non-invasive liver diagnostic and monitoring tests for NASH. Portal Hypertension is currently being used as an endpoint in several therapeutic clinical trials for the treatment of NASH.”

Exalenz plans to launch additional clinical studies for the diagnosis and monitoring of additional liver indications in the near future, including hepatocellular carcinoma (HCC), and to participate in studies for acute liver failure (ALF) and therapeutic NASH studies. These goals 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.

About Non-Alcoholic Steatohepatitis (NASH)

NASH is the most serious form of non-alcoholic fatty liver disease (NAFLD), characterized by the buildup of extra fat in liver cells that is not related to alcohol consumption[i]. NASH dramatically increases the risks of cirrhosis, liver failure, and hepatocellular carcinoma (HCC), and is an increasingly frequent reason for liver transplantation[ii]. Currently, a liver biopsy is the only way to definitively diagnose the condition.

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[i] http://www.liverfoundation.org/abouttheliver/info/nafld/
[ii] http://www.worldgastroenterology.org/assets/export/userfiles/2012_NASH%20and%20NAFLD_Final_long.pdf