# Exalenz Bioscience Announces Collaboration with ALF Study Group to use BreathID® to Monitor Patients with Acute Liver Failure

## Another step in validating BreathID® as an accurate non-invasive diagnostic solution in the broad and expanding field of liver disease

Modi'in, Israel – March 14, 2016 – 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 a collaboration with the Acute Liver Failure Study Group (ALFSG) to study the ability of the BreathID® Methacetin Breath Test (MBT) to predict patient outcome in Acute Liver Failure (ALF).

ALF is a rare but devastating condition, defined as the rapid loss of liver cell function without prior existing liver disease that results in many cases in liver transplantation as the only lifesaving resort.

The multicenter clinical study led by Professor William M. Lee, M.D., a renowned liver disease expert from UT Southwestern Medical Center and founder of the ALFSG, is expected to recruit up to 200 ALF patients over two years at 12 sites in the USA. The U.S. Food and Drug Administration (FDA) has recently approved the use of BreathID® with an investigational device exemption (IDE). In the study, up to five breath tests will be performed per patient during the first week of hospitalization. The study is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), an NIH Institute, while Exalenz will supply the required BreathID® devices and dedicated test kits.

ALF patients are typically monitored in the Intensive Care Unit with clinical and laboratory tests, which in many cases are insufficient to determine if a liver transplant is required or spontaneous recovery can be expected. In an initial ALF study performed in Hadassah Medical Center in Jerusalem and Kings College in London in 2013, it was shown that BreathID® breath test results can provide important information to assist the treating physician in predicting rapid deterioration and the need for liver transplant, as opposed to high probability of recovery.

"We are looking forward to assessing the technological abilities of BreathID and how it can improve physician decision making when treating ALF patients" said Professor William M. Lee, M.D. "Over the years, the ALF Study Group has been able to better understand ALF disease progression and to improve patient survival dramatically. We believe that the breath test information can potentially supply an additional tool to diagnose these critically ill patients, and the BreathID prove technologically beneficial in disease progression prediction."

Raffi Werner, Exalenz Bioscience CEO noted: "We are pleased to announce this collaboration with the leading group of ALF researchers. This study is another important step in evaluating the advantages of BreathID® as a non-invasive and accurate diagnostic and monitoring tool with lifesaving potential, in the broad field of liver disease."

This study is part of Exalenz's growing clinical pipeline of investigational diagnostic applications utilizing BreathID® to diagnose serious liver diseases. In addition to two trials related to NASH diagnostics and monitoring, the company has ongoing clinical trials for detection of primary liver cancer (Hepatocellular Carcinoma - HCC) and diagnosis of Clinically Significant Portal Hypertension (CSPH).

**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 and is in use in over 350 US medical centers. Exalenz holds regulatory approvals in Europe the US, China and Israel for H. pylori detection and is currently in the process of obtaining approvals for additional applications.
Additional information is available at http://www.exalenz.com.

**About the ALF Study Group**

The Acute Liver Failure Study Group (ALFSG) was founded at UT Southwestern Medical Center at Dallas in 1997 to study this rare orphan condition. The group consists of 13 North American academic sites, all tertiary-care liver transplant centers. ALFSG is funded largely by the National Institutes of Health with additional support from the Food and Drug Administration, private donors and foundations. The administrative offices are at UT Southwestern Medical Center at Dallas, and the Data Coordinating Center is at the Medical University of South Carolina.
Additional information is available at http://www.utsouthwestern.edu/labs/acute-liver.

**About Acute Liver Failure**

Acute Liver Failure (ALF) is defined as the rapid development of hepatocellular dysfunction, specifically coagulopathy and mental status changes in a patient without preexisting known liver disease. ALF can potentially lead to rapid deterioration of liver function and in many cases requires emergency liver transplantation. About 2,000 people in the U.S. develop acute liver failure (ALF) each year. The most common cause is liver injury due to excessive acetaminophen (APAP), the common pain reliever found in innumerable over-the-counter medications. Additional common causes include drug induced liver injury and viral hepatitis.

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