Exalenz Bioscience Announces New Published Data Confirming the Clinical Utility of its BreathID® Test for Detecting H. Pylori in an Emergency Department Setting

Study results support a test-and-treat strategy that could benefit symptomatic patients

Modi'in, Israel – April 13, 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 new published data supporting the use of the Company's point-of-care BreathID urea breath test for diagnosing Helicobacter pylori infection (*H. pylori)* in the emergency department (ED) setting. The study was published online in *Annals of Emergency Medicine on March 24.*

"We are encouraged by these study results, confirming the clinical utility of the BreathID test for H. pylori as part of a successful test-and-treat strategy in the emergency room," said Larry Cohen, CEO of Exalenz Bioscience. "Approximately two thirds of the world's population is infected with H. pylori, which is frequently undiagnosed and untreated, and we believe that our novel, non-invasive test will not only help diagnose patients rapidly and inexpensively at the point of care, but could also accelerate delivery of treatment to patients who need immediate medical intervention."

The prospective cohort study, developed to examine the feasibility of a test-and-treat strategy for *H. pylori* infection, enrolled 212 patients from an urban academic medical center ED with a previously established high prevalence of *H. pylori*. Symptomatic patients received the BreathID test, and those who tested positive were prescribed standard of care triple therapy medication (omeprazole, clarithromycin and amoxicillin). All participants were given a baseline questionnaire detailing general demographic information and nature of pain severity, and those testing positive for *H. pylori* were also asked additional questions about their medication adherence. Enrolled participants were contacted by telephone two weeks following the initial assessment with the same questions.

Forty-nine patients (23%) (95% confidence interval [CI] 18% to 30%) had a positive result, 33 of 49 (67%) (95% CI 53% to 79%) self-reported receiving the triple therapy medication as prescribed at follow-up, 23 of 49 (47%) (95% CI 34% to 61%) were retested, and the eradication rate of *H. pylori* was 87% (n=20/23)(95% CI 68% to 95%) in patients who returned for a retest and reported medication compliance. Additionally, there was a significant reduction in pain severity, regardless of *H. pylori* infection status.

A recent publication in *Expert Review of Molecular Diagnostics* noted that standard serological tests for detecting *H. pylori* may be suboptimal due to lack of overall accuracy, and are consequently not recommended by the U.S., European and Asia-Pacific Consensus Guidelines. In addition, antibody titers may decrease up to 6 months after successful treatment, limiting the use of the test for post-eradication confirmation[1].

"While a test-and-treat approach to H. pylori infection is currently not the standard of care in the emergency room, these data demonstrate that this strategy is viable and may confer additional benefits including early identification and treatment of peptic ulcer disease, and potential to eradicate cases of infection that could lead to an increased risk of developing gastric cancer," said Andrew Meltzer, M.D., George Washington University Department of Emergency Medicine and principal investigator of the study. "Furthermore, the BreathID test is a noninvasive, accurate and rapid test for confirming H. pylori infection and is particularly well suited for use at the point-of-care in the emergency department because it offers the significant clinical advantage of only detecting active infection, unlike standard antibody-based testing platforms."

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 gastrointestinal and liver applications.

About Helicobacter Pylori

Helicobacter pylori (H. pylori), is a Gram-negative, microaerophilic bacterium found in the stomach and linked to the development of various digestive conditions as well as peptic ulcers and gastric cancer. According to reports, approximately 20% of people under 40 years old and half of adults over 60 years old in the U.S. are infected, with higher rates in developing countries. Usually, *H. pylori* is diagnosed using a blood test. Use of blood testing is limited, however, as it is more invasive and doesn't directly detect the presence of the bacteria. For these and other reasons, leading practice associations like the ACG recommend breath testing as a non-invasive choice for the diagnosis, management and eradication of H. pylori.

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[1] *Expert Rev. Mol. Diagn.* Early online, 1–14 (2015)