



Exact Sciences Initiates Enrollment of Large Prospective CRC Screening Trial
Data from study will be submitted to FDA in support of company's PMA submission

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Madison, WI – Exact Sciences (Nasdaq: EXAS) today announced the initiation of the pivotal trial for the company's multi-marker molecular diagnostic screening test for the early detection of colorectal cancer. The multi-center DeeP-C study (Multi-Target Colorectal Cancer Screening Test for the Detection of Colorectal Advanced Adenomatous Polyps and Cancer) will generate data to support Exact Sciences' planned PMA submission to the U.S. Food and Drug Administration (FDA). The company began enrolling patients in the study on June 30th, 2011. Exact Sciences is planning to have approximately 60 sites in the United States and Canada participate in the study. Those sites are expected to enroll more than 10,000 patients between the ages of 50 and 84 who are at average risk for colorectal cancer.

Colorectal cancer is the second leading cancer killer in the United States. It is often considered the most preventable, yet least prevented cancer. Colorectal cancer is highly treatable if found early, but 40 percent of adults age 50 and older have not been screened as recommended.

"The Exact Sciences test could be an important tool in the fight against colorectal cancer. The DeeP-C trial is an opportunity to prospectively demonstrate the test's effectiveness in a large average risk patient population," said principal study investigator Thomas Imperiale, M.D. professor of medicine and associate director for research for the division of gastroenterology at Indiana University School of Medicine. "Colorectal cancer is a treatable disease if caught early, and this test shows promise as a potential addition to other available screening tools."

The latest American Cancer Society colorectal cancer screening guidelines include sDNA testing as a recommended screening option. The Exact CRC screening test, an investigational device, works by detecting specific altered DNA sequences in cells that are shed from the lining of the colon into the stool from pre-cancerous or cancerous lesions. The test also includes a hemoglobin detection component which identifies the presence of blood in the stool, another possible indicator of colorectal cancer.

"We look forward to the results of this clinical trial. There remains a significant unmet medical need to provide additional options for patients at average risk for CRC. We believe this test could become a great tool for the early detection of this terrible disease and help many of the thousands of patients who are currently not getting screened," said Kevin T. Conroy, president and chief executive of Exact Sciences.

The Exact CRC screening test is an investigational device and is not available for sale in the United States.



About the Study

The primary objective of this multi-center, prospective study is to determine the sensitivity and specificity of the Exact Sciences multi-marker molecular diagnostic screening test for colorectal cancer (CRC), using colonoscopy as the reference method. Lesions will be confirmed as malignant by histopathologic examination.

Patients at average risk of developing colorectal cancer and eligible to undergo colorectal cancer screening will be invited to participate. After providing written consent to participate in the study, subjects will be provided with a stool collection kit, and will collect stool samples for the Exact CRC screening test and for a commercially-available fecal immunochemical test or FIT test. Subjects will undergo colonoscopy within 90 days of enrollment. Subjects and physicians will remain blinded to the results of the Exact CRC screening test and the FIT test, which will not be used in subject management.

About Colorectal Cancer

Colorectal cancer is the second leading cancer killer in the United States. The National Cancer Institute estimates there will be about 142,000 new cases of colorectal cancer diagnosed in 2010 and that more than 51,000 people will die from colon and rectal cancer this year. The American Cancer Society recommends that all Americans start getting tested for the disease at age 50. However, many patients do not comply fully with current screening recommendations. In fact, 60 percent of patients today are diagnosed with colorectal cancer in the late stages, primarily because of poor screening compliance.

About Exact Sciences

Exact Sciences is a molecular diagnostics company focused on colorectal cancer. The company has exclusive intellectual property protecting its non-invasive, molecular screening technology for the detection of colorectal cancer. Stool-based DNA (sDNA) technology is included in the colorectal cancer screening guidelines of the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer. For more information, please visit the company's website at www.exactsciences.com.

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expected license fee revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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