

Exact Sciences Completes Enrollment of DeeP-C Clinical Trial for Colorectal Cancer Screening

The Associated Press

MADISON, Wis.--(BUSINESS WIRE)--Nov 15, 2012--Exact Sciences Corp. (Nasdaq: EXAS) today announced it has completed patient enrollment in its DeeP-C pivotal trial for colorectal cancer screening. The study enrolled more than 12,700 patients at sites in the United States and Canada.

Senior Research Associate II Tanya Quint at work in the Exact Sciences' lab in Madison, Wis. (Photo: Business Wire) The DeeP-C study, one of the largest of its kind, is evaluating the accuracy of the company's stool DNA colorectal cancer screening test, comparing it to traditional screening methods. It is being conducted among a population of patients between the ages of 50 and 84 at average risk of colorectal cancer. The results of the DeeP-C trial are expected to form the basis for submitting the non-invasive test for Pre-Market Approval with the U.S. Food and Drug Administration.

"We are pleased to have completed enrollment for one of the largest and most scientifically rigorous colorectal cancer screening trials ever implemented," 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. "A patient-friendly test that detects cancer and advanced polyps early may well have a significant impact in the fight against colorectal cancer." "This is a major milestone for Exact Sciences and a significant step forward in the early detection of colorectal cancer," said Kevin T. Conroy, president and chief executive of Exact Sciences. "Colorectal cancer is often considered the most preventable, yet least prevented cancer. It is highly treatable if found early, but 40 percent of adults age 50 and older have not been screened as recommended. Closing enrollment in our DeeP-C study draws Exact Sciences one step closer to bringing a potentially life-saving test to market, something the entire company remains passionate about." DeeP-C Builds on Previous Study Results The company recently presented results of a 1,003-patient case-control study that used the same technology as the DeeP-C trial. This data was presented in October, 2012 to a meeting of the American Association for Cancer Research and included patients at 36 study centers. Among the study population, there were 93 cases of colorectal cancer, 114 cases of advanced pre-cancers and 796 controls. At a nominal specificity of 90 percent, the Exact Sciences test detected 98 percent of colorectal cancers and 83 percent of pre-cancers with high-grade dysplasia, the majority of which progress to cancer. The test demonstrated 57 percent sensitivity in the detection of advanced pre-cancers equal to or larger than 1 centimeter. The test's sensitivity increased with the size of the pre-cancers, rising to 83 percent for pre-cancers larger than 3 centimeters.

About Stool-Based DNA Screening Normal cells, cancer cells, and pre-cancer cells

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are shed from the colon lining into the stool stream every day. As these cells degenerate, they release DNA. DNA that originates from cancers and pre-cancers has abnormalities that can be identified by Exact Sciences' sDNA test. Patients using Exact Sciences' test collect a stool sample at home and send it to a clinical laboratory. Using Exact Sciences' process, the laboratory can isolate the human DNA and identify specific altered and mutated DNA targets, known to be associated with colorectal cancer and pre-cancer, and report the findings. The American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer included sDNA technology in the colorectal cancer screening guidelines.

Exact Sciences' sDNA test is an investigational device and is not available for sale in the United States. Results of the DeeP-C trial will be reported when available.

About Colorectal Cancer Colorectal cancer, commonly known as colon cancer, is the second leading cause of cancer deaths in the United States and the most deadly cancer among non-smokers. There are nearly 143,000 colorectal cancer cases diagnosed and 52,000 deaths due to this disease each year. Roughly one-third of colorectal cancer-related deaths could be avoided with regular screening. Of those diagnosed, nearly half are expected to die within five years because most cases are detected when cancer has progressed and is less treatable. For those whose cancer is detected at an earlier stage, the five-year survival rate can be greater than 90 percent.

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.

Certain statements made in this news release contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, which are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. Forward-looking statements in this news release may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, anticipated results of our pivotal clinical trial, expectations concerning our ability to secure FDA approval of Exact Sciences' sDNA test, 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

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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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