Top-Line Data Show Exact Sciences’ Cologuard Test Demonstrates 92 Percent Sensitivity in the Detection of Colorectal Cancer

The Associated Press

MADISON, Wis.--(BUSINESS WIRE)--Apr 18, 2013--Exact Sciences Corp. (Nasdaq: EXAS) today announced that preliminary analysis shows that the company’s Cologuard colorectal cancer screening test met or exceeded all primary and secondary endpoints of its recently completed DeeP-C pivotal clinical trial. The clinical trial evaluated the test’s use for the detection of colorectal cancer and pre-cancerous polyps.

Senior Research Associate Tanya Quint loads one of the instruments used to run Exact Sciences' Cologuard test at the company's headquarters in Madison, Wis. (Photo: Business Wire) Preliminary, top-line data show that Cologuard demonstrated 92 percent sensitivity for the detection of colorectal cancer and 42 percent sensitivity for the detection of pre-cancerous polyps, including 66 percent sensitivity for polyps equal to or greater than 2 centimeters. The test achieved a specificity of 87 percent during the trial.

Sensitivity measures a test’s ability to correctly identify positive results. It is the percentage of patients who were determined by colonoscopy to have pre-cancerous polyps or cancer who had a positive Cologuard test result. Specificity measures a test’s ability to correctly identify negative results. It is the percentage of patients who were determined by colonoscopy not to have pre-cancerous polyps or cancer who had a negative Cologuard test result.

According to the Journal of the National Cancer Institute, colorectal cancer is often considered the most preventable, yet least prevented cancer. But nearly 50 percent of those age 50 and older have not been screened as recommended. As a result, colorectal cancer is the second leading cause of cancer death in the United States.

The company’s pivotal DeeP-C trial included 10,000 patients between the ages of 50 and 84 who were at average risk for colorectal cancer. Enrollment was conducted at 90 sites to gain a broad demographic sampling of patients. The study is one of the most extensive colorectal cancer screening studies ever conducted in the United States. It compared the performance of the Cologuard test to colonoscopy and fecal immunochemical testing or FIT.

“The DeeP-C trial evaluated Cologuard’s ability to detect both pre-cancerous polyps and cancer in a large, average-risk patient population,” said principal study investigator Thomas F. Imperiale, M.D., professor of medicine, associate director for research for the division of gastroenterology at Indiana University School of Medicine and a member of the IU Simon Cancer Center. “There is a significant unmet clinical need for an accurate, convenient, non-invasive colorectal cancer

screening test. The data from the DeeP-C trial are very promising. Cologuard may well be a future solution for identifying slow growing polyps much before they develop into cancer." "We are extremely pleased with these results, which we believe strongly support the power and potential clinical use of the Cologuard screening test," said Kevin T. Conroy, president and chief executive of Exact Sciences. "We believe our test could become a great tool in the fight against this terrible disease." Exact Sciences will submit data from the DeeP-C study to the U.S. Food and Drug Administration as part of its pre-market approval (PMA) submission. Later this year, the company also will submit the study's complete data set for publication in a peer-reviewed journal, presentation at a major medical meeting or both.

The DeeP-C clinical trial achieved all of its endpoints. The co-primary endpoints for the Deep-C study were the sensitivity and specificity of the Cologuard screening test for colorectal adenocarcinoma. The trial included two sets of co-secondary endpoints. The first included sensitivity and specificity of the test for advanced adenomas. The second included non-inferiority of Cologuard to FIT for cancer sensitivity and superiority to FIT for advanced adenoma sensitivity.

Each patient result from the Cologuard test was compared to the patient's colonoscopy result and the histopathologic diagnosis of any lesions that were discovered during colonoscopy and biopsied. The study population included 64 cancer patients and 752 patients with pre-cancerous polyps.

Exact Sciences' Cologuard screening test is designed to detect specific changes in a patient's DNA that appear in the stool and often indicate the presence of colorectal cancer or the pre-cancerous polyps most likely to develop into it. The test also identifies the presence of blood in the stool, another indicator of possible colorectal cancer. The latest American Cancer Society colorectal cancer screening guidelines include stool-based DNA testing as a recommended screening option.

The Exact Sciences' screening test is an investigational device and is not available for sale in the United States. The scientific information discussed in this news release related to our Cologuard test is preliminary and investigative, pending additional analysis by the company and review by the FDA.

Deep-C Pivotal Clinical Trial Results Webcast & Conference Company management will host a webcast and conference call on Thursday, April 18, 2013, at 7:30 a.m. ET to discuss the preliminary, top-line results of its DeeP-C clinical trail. The webcast will be available at www.exactsciences.com. Domestic callers should dial 877-212-6082 and international callers should dial 707-287-9332. An archive of the webcast and a replay of the conference call will be available at www.exactsciences.com or by calling 855-859-2056 domestically or 404-537-3406 internationally. The access code for the conference call and replay is 45786044. The conference call, webcast and replay are open to all interested parties.

About Exact Sciences Corp.
Exact Sciences Corp. is a molecular diagnostics company focused on the early detection of colorectal cancer. The company has exclusive intellectual property

protecting its convenient, non-invasive stool-based DNA technology for the detection of colorectal cancer. Stool-based DNA 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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