

FDA Approves Exact Sciences' Cologuard®; First and Only Stool DNA Noninvasive Colorectal Cancer Screening Test

First time in history a technology receives FDA approval and proposed national coverage by CMS on the same day

Screening test detects 92% of colorectal cancer

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Exact Sciences Corp. →

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MADISON, Wis., Aug. 12, 2014 /PRNewswire/ -- **Exact Sciences Corp.** (NASDAQ: **EXAS**) announced today that the U.S. Food and Drug Administration (FDA) has approved Cologuard, the company's noninvasive, stool DNA colorectal cancer screening test. Cologuard is the first noninvasive screening test for colorectal cancer that analyzes both stool DNA and blood biomarkers and has been proven to find 92 percent of cancers and 69 percent of the most advanced precancerous polyps in average risk patients. Cologuard, which is available through healthcare providers, offers people 50 and older at average risk for colorectal cancer an easy-to-use screening test they can do in the privacy of their own home.

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FDA approves first noninvasive DNA screening test for colorectal cancer (PRNewsFoto/Exact Sciences Corp.)

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Upon approval, Exact Sciences also received a proposed coverage memorandum from the Centers for Medicare and Medicaid Services (CMS). Cologuard is the first product to take part in the joint FDA and CMS parallel review pilot program in which both agencies simultaneously review medical devices to help reduce the time between FDA approval and Medicare coverage. A final National Coverage Determination is expected to be posted in October/November of this year after a public comment period.

Colorectal cancer is considered the most preventable, yet least prevented cancer due to the lack of patient compliance with screening. An estimated 23 million Americans between 50 and 75 are not getting screened as recommended and as a result, colorectal cancer remains



the second-leading cancer killer in the U.S. For those whose cancer is detected at an earlier stage, the five-year survival rate can be greater than 90 percent.

"Colorectal cancer is highly preventable and following the recommended screening guidelines can lead to life-saving early detection," said Eric Hargis, CEO, Colon Cancer Alliance. "In more than 60 percent of all cases, colorectal cancer is not detected until its late stages, making treatment more challenging. New, patient-friendly screening options are desperately needed to prevent colorectal cancer or help identify it early, when it is most treatable. Given that more than half of colorectal cancer-related deaths could be avoided with regular screenings, having Cologuard as another option for people who have resisted getting a colonoscopy could result in many lives being saved and screening compliance rates to increase."

Cologuard is designed to detect biomarkers from DNA in cancer that is shed from the colon as part of the digestive process and blood released in the stool. After the physician orders Cologuard, the kit is mailed directly to the patient's home. The patient then collects a stool sample in the Cologuard Collection Kit and sends the kit back to the Exact Sciences lab for testing through a pre-paid mailer.

At the lab, the stool sample is analyzed in an automated system to yield a single test result—positive or negative for the presence of precancerous polyps or cancer. Results from the Cologuard test are turned around in as little as two weeks, and patients learn their results directly from their prescribing physician. Unlike many other screening options, Cologuard does not require medication or dietary restrictions, or bowel preparation prior to taking the test.

"The robustly conducted research as part of this FDA approval process has proven that this noninvasive test is highly sensitive in detecting both early stage colorectal cancer and the most advanced precancerous polyps most likely to develop into cancer," said David Ahlquist, M.D., a Mayo Clinic gastroenterologist and co-inventor of the test. "The test is designed for high accuracy, ease of patient use, and wide accessibility. We hope that it will make a difference and save many lives."

"The FDA approval of Cologuard represents a major achievement in Exact Sciences' mission to make a noninvasive, patient-friendly screening test for colorectal cancer available," said Kevin Conroy, President, CEO and Chairman of Exact Sciences. "Cologuard addresses a critical need for a more convenient screening option for patients to aid in prevention and early detection. Exact Sciences is committed to making Cologuard available and accessible to patients and looks forward to advancing cancer detection in other gastrointestinal cancers. On behalf of the Exact Sciences team, I would like to thank the FDA and CMS for allowing us to go through the parallel review process."

Results from the company's DeeP-C Study, prospective, 90-site, 10,000-patient pivotal study—one of the most extensive colorectal cancer screening studies ever conducted in the U.S.—were published in April 2014 in the *New England Journal of Medicine's*, "**Multi-target Stool DNA Testing for Colorectal-Cancer Screening**".

Cologuard is available to patients through their healthcare providers in the U.S. for \$599. Exact Sciences has plans to make Cologuard available in select countries in Europe pending CE Mark. For more information, visit **www.CologuardTest.com** or call 1-844-870-8870. More information on colon cancer and the importance of screening and early detection at **<http://www.beseengetscreened.com/>**. Visit **www.exactsciences.com** to sign up for the company's eNewsletter.

Dr. David Ahlquist, professor of medicine at Mayo Clinic, is the inventor of the technology that has been licensed to Exact Sciences from Mayo Clinic. Under that licensing agreement, Mayo Clinic and Dr. Ahlquist share in equity and royalties. Revenue Mayo Clinic receives is used to support Mayo's not-for-profit mission in patient care, education and research.

About Exact Sciences Corp.

Exact Sciences Corp. (NASDAQ: **EXAS**) is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. The company has exclusive intellectual property protecting its noninvasive, molecular screening technology for the detection of colorectal cancer. Stool 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, follow us on Twitter [@ExactSciences](https://twitter.com/ExactSciences) or find us on [Facebook](https://www.facebook.com/ExactSciences).

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 that 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, our ability to secure favorable reimbursement rates from Medicare and other third-party payors, timing of our launch of a commercial product, our estimates of the available market size and our potential penetration, 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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