Geneoscopy's Noninvasive Colorectal Cancer Screening Test Demonstrates High Sensitivity and Specificity in Large Pivotal Clinical Trial

Colorectal Cancer and Advanced Adenoma Sensitivity Results are the Highest Reported from any Prospective Pivotal Study for a Noninvasive Screening Test

Innovative RNA Biomarker Screening Test's Premarket Approval Submission Planned for Early Q1 2023

ST. LOUIS, Jan. 10, 2023 /PRNewswire/ -- Geneoscopy Inc., a life sciences company focused on the development of diagnostic tests for gastrointestinal health, today announced favorable results from the CRC-PREVENT trial – a pivotal clinical trial evaluating the efficacy of its noninvasive, stool-based, at-home diagnostic screening test to detect colorectal cancer (CRC) and advanced adenomas (AA) in average-risk individuals. In the trial, Geneoscopy's stool-based screening test met the clinical endpoints across all primary outcome measures, including sensitivity and specificity for CRC and AA.

The CRC-PREVENT trial included 8,289 individuals with diverse racial, ethnic, and socioeconomic backgrounds across more than 2,900 zip codes in all lower 48 states, with colonoscopies performed in more than 3,800 endoscopy centers, which reflect the diversity of gastroenterology practices across America. Efficacy results from the study include:

- 94% sensitivity for detecting CRC
- 45% sensitivity for detecting AA
- 88% specificity for no findings on a colonoscopy

These sensitivity results are the highest reported for any noninvasive CRC screening test in any prospective registrational clinical study completed to date. Of note, CRC-PREVENT is the first prospective clinical study wherein a stool-based test demonstrated the ability to detect CRC amongst 45-49-year-olds in a US population.[1] Additionally, CRC and AA sensitivity performance results for Geneoscopy's test exceed those

recently reported from a large clinical study for a blood-based test.[2] Moreover, a recent study suggests, when given a choice, patients are more willing to comply with a stool-based screening test than a blood-based test. This was primarily attributed to the greater ability to complete a stool test at home.[3]

Importantly, given Geneoscopy's decentralized clinical trial approach, the demographics of the patients who enrolled and completed the CRC-PREVENT study are more reflective of the socioeconomic and racial diversity of the country than most conventional, centralized trials. The diversity of the patient cohort confirms the test's performance across different demographic groups and advances the important goal of increased access to healthcare innovation for historically underserved populations.

Geneoscopy's test, performed in its St. Louis laboratory, uses a novel, proprietary method to stabilize and extract eukaryotic RNA biomarkers from stool samples that may allow for improved diagnosis and management of gastrointestinal diseases such as CRC. The FDA granted the test its Breakthrough Designation in January 2021.

"The use of our patented RNA biomarker technology is a first in CRC screening. The large-scale prospective clinical study data demonstrate that this noninvasive CRC screening test can accurately detect if people have cancer *and* if they have advanced adenomas that put them at higher risk of developing cancer. These results provide further evidence that our test may allow patients to get appropriate treatment, in some cases, even before cancer develops," said Dr. Erica Barnell, Chief Science Officer and Geneoscopy's co-founder. "Our sincerest gratitude goes to all who participated in or were involved with this trial. We look forward to submitting a Premarket Approval application to the FDA to make this cutting-edge innovation available to the millions of Americans eligible to be screened for CRC."

Despite CRC being this country's second leading cause of cancer death, millions of eligible Americans do not get screened – many due to a lack of access or avoidance of invasive options like colonoscopies.

“Colonoscopy screening rates declined during the pandemic, stressing the need for noninvasive screening options. That’s why noninvasive tests, allowing for collection to be done at home, have become a critical tool in the battle against CRC, as they make screening easier and more accessible,” noted Dr. David Lieberman, Professor of Medicine, Division of Gastroenterology and Hepatology, Oregon Health Sciences University School of Medicine, and past president of the American Gastroenterology Association.[4] "Geneoscopy’s test and the positive clinical trial results are promising because patients need additional convenient options that will accurately detect colon cancer, as well as advanced adenomas, before patients have cancer. If we can identify patients with advanced adenomas and remove those lesions, many cancers can be prevented. I'm hoping to have a new and highly reliable test available for patients soon – one that will allow them to conveniently screen for CRC in their own homes."

Geneoscopy’s test is not yet available for sale and is not yet approved by the U.S. Food and Drug Administration (FDA). A Premarket Approval submission to the FDA is planned for the first quarter of 2023.

About CRC-PREVENT

CRC-PREVENT was a Phase 3 prospective, single-arm study designed to evaluate the efficacy of Geneoscopy’s noninvasive, at-home diagnostic screening test to detect colorectal cancer and advanced adenomas in average-risk individuals aged 45 years and older. Using a collection kit, participants submitted self-collected stool samples via express delivery and underwent an optical colonoscopy examination. All significant lesions discovered during the colonoscopy were biopsied or removed and sent for histopathology. A comparative analysis was conducted to determine sensitivities and specificities for colorectal cancer, advanced adenomas, non-advanced adenomas, benign hyperplastic polyps, and colonoscopies with no findings.

About Colorectal Cancer & Screening

Responsible for over 50,000 deaths annually, colorectal cancer (CRC) is the second leading cause of cancer death in the United States. CRC usually begins as a growth (or polyp) that may or may not develop into cancer over time. Early detection and treatment are crucial to improve survival; however, many newly diagnosed patients suffer from advanced disease. Colonoscopy remains the gold standard for CRC screening in the U.S. Yet this method is frequently met with patient aversion due to its required bowel preparation, sedation, and potential time away from work. Currently available noninvasive screening methods demonstrate lower sensitivity to detect early-stage CRC and high-risk precancerous lesions, including advanced adenomas, which are estimated to be a precursor in 95 percent of CRC cases.[5]

About Geneoscopy Inc.

Geneoscopy Inc. is a life sciences company focused on developing diagnostic tests for gastrointestinal health. Leveraging its proprietary, patented stool-derived eukaryotic RNA (seRNA) biomarker platform, Geneoscopy's mission is to empower patients and providers to transform gastrointestinal health through innovative diagnostics. Beyond colorectal cancer screening, Geneoscopy is developing tests for diagnosis, treatment selection, and therapy monitoring in other disease areas in partnership with leading universities and biopharmaceutical companies. For more information, visit www.geneoscopy.com and follow the company on LinkedIn.

Geneoscopy Inc. Forward-Looking Statements

The information in this release includes information about Geneoscopy's future plans concerning its noninvasive molecular test that can detect colorectal cancer and precancerous adenomas, which constitute forward-looking statements. These forward-looking statements are based on the Company's reasonable estimates of future results or trends. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict, many of which are outside the Company's control. Geneoscopy's actual results and financial condition may differ materially from those indicated in the forward-looking

statements. Although the Company believes that its business plans and objectives reflected in or suggested by these forward-looking statements are reasonable, such plans or objectives may not be achieved, and the actual results may differ substantially from the projected results.

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3. Young GP, Chen G, Wilson CJ, et al. "Rescue" of Nonparticipants in Colorectal Cancer Screening: A Randomized Controlled Trial of Three Noninvasive Test Options. Cancer Prev Res (Phila). 2021;14(8):803-810. doi:10.1158/1940-6207.CAPR-21-0080

4. Dr. David Lieberman is a member of Geneoscopy's Scientific Advisory Board.

5. Lin JS, Piper MA, Perdue LA, et al. Screening for Colorectal Cancer: A Systematic Review for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Jun. (Evidence Syntheses, No. 135.) 1, Introduction. Available from: https://www.ncbi.nlm.nih.gov/books/NBK373586/