



## **JAMA Publishes Geneoscopy's Pivotal CRC-PREVENT Trial Results, Reporting Highest Sensitivity for Detecting Colorectal Cancer and Advanced Adenomas Among Available Noninvasive Screening Tests**

- *Geneoscopy's noninvasive, multi-target, stool RNA (mt-sRNA) colorectal cancer screening test showed extraordinary sensitivity for detecting early-stage (Stage 1) colorectal cancer at 100% and advanced adenomas at 46%*
- *Sensitivity for CRC was 100% among individuals ages 45 to 49, an age group now recommended for screening given the rapid rise of early onset CRC*
- *Study will be presented at the American College of Gastroenterology 2023 Annual Meeting*

**ST LOUIS, MO. – Oct. 23, 2023** – Geneoscopy Inc., a life sciences company focused on developing diagnostic tests for gastrointestinal health, announced a publication in *The Journal of the American Medical Association* (JAMA), highlighting the company's pivotal CRC-PREVENT trial results. The novel study will be presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting in Vancouver, Canada, October 20-25, showcasing its highly sensitive screening test for colorectal cancer (CRC) and advanced adenomas (AA). The company will also present findings from its inflammatory bowel disease research at the meeting.

"Although colorectal cancer is the second deadliest cancer in the U.S., millions of eligible Americans do not get screened due to a lack of access or avoidance of invasive options like colonoscopies," said Erica Barnell, MD, PhD, Chief Science and Medical Officer at Geneoscopy. "Geneoscopy is dedicated to addressing this challenge and improving access to a reliable, noninvasive CRC screening test, especially as incidence is rising among younger populations. Providing reliable tools for early detection allows providers to intervene and start treatment earlier, potentially saving patients' lives."

The CRC-PREVENT trial evaluated 8,920 participants (ages 45 and older) using Geneoscopy's novel mt-sRNA test. CRC was detected with 94% sensitivity, including 100% sensitivity for early-stage (Stage I) CRC. The test also detected AAs with a 46% sensitivity, rising to 50% for AAs over two centimeters in size. Notably, for younger participants (ages 45 to 49), CRC sensitivity was 100% and AA sensitivity was 45%. The study published in JAMA, "CRC-PREVENT: Multi-target Stool RNA Test for Colorectal Cancer Screening," will be presented at ACG by study co-author David Lieberman, MD, Oregon Health & Science University.

"CRC rates are climbing among younger populations less than 50 years old, prompting a recent shift in screening guidelines from the USPSTF to initiate screening at age 45 years. There is a notable gap in data regarding the efficacy of noninvasive screening tests for this age group, including the sensitivity for colorectal cancer (CRC) and advanced adenomas," said Dr. Lieberman. "This prospective pivotal study of a new stool-derived RNA test demonstrates excellent sensitivity for CRC and advanced adenomas across the entire age spectrum of adults eligible for CRC screening, including ages 45 to 49. Geneoscopy's technology can potentially provide millions of people with a convenient and reliable option for detecting and preventing CRC."

Geneoscopy will also present results at ACG from a recent study predicting therapeutic response and monitoring for mucosal healing for patients with Inflammatory Bowel Disease (IBD) using the company's RNA technology.

"Geneoscopy's research and development efforts come at a critical time when 60-70 million Americans suffer from GI diseases, including CRC and IBD," said Vince Wong, JD, MBA, Chief Commercial Officer at Geneoscopy. "These studies are an example of our commitment to drive research and product development leveraging our proprietary RNA technology to help prevent, detect, monitor, and improve treatment for gastrointestinal diseases."

Geneoscopy has submitted a Premarket Approval Application (PMA) to the FDA for its noninvasive, multi-target, stool RNA (mt-sRNA) colorectal cancer screening test.

### **Geneoscopy's Presentations at ACG 2023**

#### **Oral Presentation:** *CRC-PREVENT: Multi-target Stool RNA Test for Colorectal Cancer Screening*

Session: Plenary Session 3B – General Endoscopy / Practice Management / Colorectal Cancer Prevention

Date & Time: Tuesday, October 24, 2023, from 2:25–2:35 p.m. PT (UTC -7)

Location: Ballroom B

#### **Scientific Poster Presentation:** *Stool-derived Eukaryotic RNA Biomarkers for Predicting Therapeutic Response and Monitoring Mucosal Healing for Patients with Inflammatory Bowel Disease*

Session: Scientific Poster Session – Open & Authors Present

Date & Time: Sunday, October 22, 2023, from 3:30–7 p.m. PT (UTC -7)

Location: Exhibit Hall

### **About CRC-PREVENT Trial**

CRC-PREVENT was a pivotal 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 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](http://www.geneoscopy.com) and follow the company on [LinkedIn](#).

### **Geneoscopy Inc. Forward-Looking Statements**

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

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