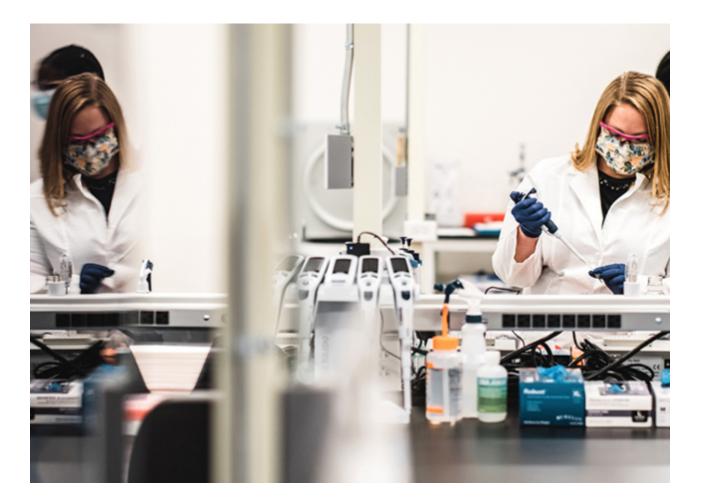# Geneoscopy Enrolls First Patients in CRC-PREVENT U.S. Pivotal Trial

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ST. LOUIS, July 12, 2021/PRNewswire/ - **Geneoscopy Inc.**, a life sciences company focused on the development of diagnostic tests for gastrointestinal health, today announced the enrollment of its first patients in the CRC-PREVENTpivotal trial. The clinical study seeks to evaluate the safety and efficacy of Geneoscopy's noninvasive, at-

home diagnostic screening test to successfully detect colorectal neoplasms, including advanced adenomas, in average-risk individuals, a group with no known co-morbidities associated with cancer risk and therefore more challenging to diagnose. The company's innovative diagnostic was granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) in January of 2020.

"We are pleased to initiate this important study and validate the use of Geneoscopy's RNA-FIT assay as a valuable noninvasive tool to help prevent cancer through routine colorectal cancer screening," commented Dr. Erica Barnell, Geneoscopy's co-founder and Chief Scientific Officer. "The ultimate goal of colorectal screening is cancer prevention, but this requires diagnostic screening options with the sensitivity to identify clinically relevant pre-cancerous lesions, including advanced adenomas. The RNA-FIT assay aims to deliver the necessary sensitivity and specificity in a simple, at-home collection kit."

The prospective, single-arm study will enroll more than 12,000 patients across all 48 contiguous United States. Patients will submit samples via the mail and subsequently undergo optical colonoscopy examination. All significant lesions discovered during colonoscopy will be biopsied or removed and sent for histopathology. A comparative analysis will be conducted to determine sensitivities and specificities, as applicable, for colorectal cancer, advanced adenomas, non-advanced adenomas, benign hyperplastic polyps, and colonoscopies without findings.

"When it comes to detecting advanced adenomas, noninvasive tests are not currently hitting a 50% threshold. Until now, only colonoscopy can detect advanced adenomas reliably," commented Dr. David Lieberman, Professor of Medicine, Division of Gastroenterology and Hepatology at the Oregon Health Sciences University School of Medicine. "A noninvasive, at-home option that successfully detects these pre-cancerous lesions would represent an important, positive step in early detection for colorectal cancer prevention."

Geneoscopy's initial clinical study demonstrated high sensitivity of its multifactor RNA-FIT assay compared with colonoscopy findings, demonstrating 95% sensitivity for colorectal cancer, 62% sensitivity for advanced adenomas, and 25% sensitivity for other non-advanced adenomas with an 85% specificity for no findings on a colonoscopy. The promising data was previously presented by Dr. Barnell, at the Association for Molecular Pathology (AMP) 2020 Annual Meeting and the peer-reviewed article recently published in *Clinical and Translational Gastroenterology*.

Responsible for over 50,000 deaths annually, colorectal cancer (CRC) is the second leading cause of cancer related death in the United States.[1] Disease progression begins with polyps that may or may not develop into cancer over time. Early detection and

treatment are crucial to improve survival; however, most newly diagnosed patients suffer from advanced disease. Colonoscopy remains the gold-standard for CRC screening in the US, yet this method is frequently met with patient aversion due to its required bowel preparation, sedation, and associated discomfort, resulting in low patient compliance. Currently available noninvasive screening methods lack sufficient levels of sensitivity to effectively and reliably detect both early-stage CRC and high-risk precancerous lesions, including advanced adenomas which are a precursor in up to 70% of CRC cases.

To learn more about the CRC-PREVENT clinical trial and join in the fight to help prevent colorectal cancer, visit https://cv.colonscreeningstudy.com/