



For Immediate Release

Clinical Genomics Announces Three Poster Presentations at ASCO 2021 Annual Meeting, Including New Data Highlighting Clinical Utility of COLVERA® Liquid Biopsy for Colorectal Cancer Recurrence Detection and Prediction of Clinical Outcomes

-- Presentations showcase clinical utility and actionability of methylation-based liquid biopsy test, COLVERA, for assessment of minimal or recurrent disease, response to therapy, and predicting clinical outcomes in patients treated for colorectal cancer --

BRIDGEWATER, N.J. — June 14, 2021 — Clinical Genomics, a provider of cancer diagnostic solutions, including liquid biopsy tests for minimal residual disease (“MRD”) and recurrence monitoring of colorectal cancer (“CRC”), announced today that three abstracts were presented at the American Society of Clinical Oncology (“ASCO”) Annual Meeting, which took place virtually from June 4-8, 2021.

“We are pleased to share these findings at this prestigious gathering of oncology specialists. COLVERA is a first of its kind blood test to detect circulating tumor DNA for MRD assessment and recurrence monitoring. The studies presented further validate the clinical benefit of our approach. Ongoing studies and monitoring have enabled us to further refine COLVERA analysis. With these improvements, COLVERA differentiates more accurately between patients with and without recurrent disease, and thus is clinically more informative. COLVERA has market leading data and the ability to save lives by providing specialists with an advanced diagnostic tool for the care of their CRC patients,” stated Betsy Hanna, President and CEO of Clinical Genomics.

Details of the three abstracts, which were included in the *Gastrointestinal Cancer – Colorectal and Anal* track, are as follows:

(1) Abstract #3546: Clinical performance of methylation-based liquid biopsy test COLVERA after optimization of test interpretation rules.

<https://meetings.asco.org/abstracts-presentations/196522>

Study highlights and conclusions:

- Included two cohorts of CRC patients (N=322 and N=144) evaluating the impact of optimizing the assay’s actionability for CRC recurrence detection.

- Improved specificity, with 98% of patients without imaging-detected recurrence being correctly identified as not having detectable COLVERA results.
- Improved positive predictive value (“PPV”) to >76%, with more than three quarters of patients with detectable COLVERA levels demonstrating imaging-confirmed recurrence at the timepoints closest to the blood draw.
- Single time-point sensitivity for recurrence detection maintained at 59%-62%.

“This change in the COLVERA interpretation rule results in optimized clinical specificity with minimal impact on sensitivity. For an assay intended to aid in CRC surveillance and early recurrence detection, improved accuracy affords physicians increased confidence in making actionable decisions based on the test result, including additional imaging or treatment,” stated Zivjena Vucetic, MD, PhD, Senior Vice President, Medical, of Clinical Genomics.

(2) Abstract #3528: Use of circulating tumor DNA in colorectal cancer patients to assess tumor burden and response to therapy: An observational study.

<https://meetings.asco.org/abstracts-presentations/198467>

- Levels of methylated *BCAT1* and *IKZF1* DNA in blood correlated with tumor burden; methylation levels decreased in all patients with complete curative intent treatment, while more than half of patients with incomplete treatment still had detectable methylated ctDNA levels.
- The test can aid in monitoring responses to therapy and identification of patients with residual cancer who might benefit from ongoing therapy and intensive monitoring.

(3) Abstract #3579: Circulating tumor DNA and circumferential resection margin as key prognostic indicators for survival in rectal cancer.

<https://meetings.asco.org/abstracts-presentations/196501>

- In rectal cancer, 92% of patients with circumferential resection margin (“CRM”) involvement had detectable levels of methylated *BCAT1* and *IKZF1* DNA.
- The presence of combined CRM and detectable ctDNA demonstrated a hazard ratio (“HR”) of 20.5 and was a predictor of lower rates of survival.
- Future studies with longitudinal ctDNA assessment pre- and post-treatment may inform prognosis and help tailor patients’ treatment.

The abstracts are currently available on ASCO’s 2021 [Meeting Library](#).

About Clinical Genomics

Clinical Genomics is dedicated to improving patient outcomes through early detection of colorectal cancer. Clinical Genomics’ products span the full spectrum of colorectal cancer testing from screening to post-treatment monitoring. Clinical Genomics is committed to developing and delivering solutions that provide physicians and their

patients with information to help guide earlier and better treatment decisions in cancer care management.

About COLVERA

COLVERA is a Laboratory Developed Test supplied by Clinical Genomics Pathology Inc., a CLIA Certified, CAP accredited laboratory in Bridgewater, NJ, USA. COLVERA is the first of its kind blood test to detect circulating tumor DNA for minimal residual disease assessment and recurrence monitoring in patients previously diagnosed with colorectal cancer. COLVERA targets aberrant methylation of two genes (*BCAT1* and *IKZF1*) and is mutation agnostic. COLVERA does not require any form of tissue biopsy. Introduced in 2017, COLVERA is the first liquid biopsy assay for CRC monitoring and has been ordered by hundreds of colorectal surgeons and medical oncologists across the United States.

About Colorectal Cancer

Colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer-related deaths in the United States, with more than 140,000 people per year expected to be diagnosed with CRC and over 50,000 succumbing to the disease annually. For patients who survive, 15%-30% will experience a recurrence, most within the first two years following primary treatment. On average, the lifetime risk of developing colorectal cancer is about one in 23 for men and women combined; however, this varies widely according to individual risk factors.

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