Natera to Present New Colorectal Cancer Data at the 2021 ASCO GI Symposium

January 12, 2021

Oral presentation showcases the largest early-stage CRC cohort to date, further validating the serial use of Signatera™ for early recurrence detection and MRD assessment

SAN CARLOS, Calif., Jan. 12, 2021 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a pioneer and global leader in cell-free DNA testing, today announced it will present new data on its personalized and tumor-informed molecular residual disease (MRD) test, Signatera, at the American Society of Clinical Oncology's 2021 Gastrointestinal Cancers Symposium (ASCO GI), taking place January 15-17, 2021.

Natera will have one oral and one poster presentation, each describing the clinical performance of Signatera in patients with colorectal cancer (CRC).

Details about the presentations are as follows:

Abstract #11 | Oral Presentation | Presenter: Tenna V. Henriksen, MS | Jan. 16, 6:00 am PST

Circulating tumor DNA analysis for assessment of recurrence risk, benefit of adjuvant therapy, and early relapse detection after treatment in colorectal cancer patients

This multi-center study evaluates the prognostic value of longitudinal circulating tumor DNA (ctDNA) monitoring with Signatera in early-stage CRC. A cohort of 265 stage I-III CRC patients was followed for approximately three years (median of 28.4 months). Plasma samples were analyzed post-surgery, after adjuvant chemotherapy, and at regular intervals thereafter. The study demonstrates that Signatera detects recurrence early, with a median lead time of eight months before clinical or radiographic relapse; and compared to all other clinical and pathological risk factors, Signatera MRD status is the only significant risk factor in predicting recurrence.

"Our study is unique in that it is, to the best of our knowledge, the largest ctDNA study in early-stage CRC, with extremely mature follow-up," said Claus Lindbjerg Andersen, PhD, Professor, Department of Molecular Medicine at Aarhus University and the study's senior author. "Through this study, we are able to demonstrate that serial ctDNA testing can detect molecular residual disease a median of eight months ahead of clinical relapse, with significant potential to improve patient care."

Abstract #102 | Poster Presentation | Principal Investigator: David Cunningham, MD | Jan. 15, 5:00 am PST

Minimal residual disease (MRD) detection with circulating tumor DNA (ctDNA) from personalized assays in stage II-III colorectal cancer patients in a U.K. multicenter prospective study (TRACC)

A prospective study on 122 patients with stage II-III CRC, who were monitored pre- and post-surgery using Signatera. Patients who were MRD-positive after surgery had a significantly higher rate of relapse than those who were MRD-negative. MRD detection rates increase with disease stage and risk features, and correlate with recurrence rates.

"We are delighted to share the results of these studies with the ASCO GI community," said Alexey Aleshin, MD, Natera's Senior Medical Director of Oncology. "These data build on our previous studies, providing yet another consistent proof point for the clinical performance of Signatera in CRC and demonstrating our commitment towards research and innovation in the MRD field."

About Signatera
Signatera is a custom-built circulating tumor DNA (ctDNA) test for treatment monitoring and molecular residual disease (MRD) assessment in patients previously diagnosed with cancer. The test is available for clinical and research use, and in 2019, it was granted Breakthrough Device Designation by the FDA. The Signatera test is personalized and tumor-informed, providing each individual with a customized blood test tailored to fit the unique signature of clonal mutations found in that individual's tumor. This maximizes accuracy for detecting the presence or absence of residual disease in a blood sample, even at levels down to a single tumor molecule in a tube of blood. Unlike a standard liquid biopsy, Signatera is not intended to match patients with any particular therapy; rather, it is intended to detect and quantify how much cancer is left in the body, to detect recurrence earlier and to help optimize treatment decisions. Signatera test performance has been clinically validated in multiple cancer types including colorectal, non-small cell lung, breast, and bladder cancers. Signatera has been developed and its performance characteristics determined by Natera, the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified.

About Natera
Natera is a pioneer and global leader in cell-free DNA testing from a simple blood draw. The mission of the company is to change the management of disease worldwide with a focus on women's health, oncology, and organ health. Natera operates ISO 13485-certified and CAP-accredited laboratories

certified under the Clinical Laboratory Improvement Amendments (CLIA) in San Carlos, California and Austin, Texas. It offers proprietary genetic testing services to inform obstetricians, transplant physicians, oncologists, and cancer researchers, including biopharmaceutical companies, and genetic laboratories through its cloud-based software platform. For more information, visit natera.com. Follow Natera on LinkedIn.

Forward-Looking Statements
All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to our efforts to develop and commercialize new product offerings, our ability to successfully increase demand for and grow revenues for our product offerings, whether the results of clinical or other studies will support the use of our product offerings, our expectations of the reliability, accuracy and performance of our tests, or of the benefits of our tests and product offerings to patients, providers and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at www.natera.com/investors and www.sec.gov.

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