Medicare Issues Positive Draft Local Coverage Determination for Natera's Signatera™ MRD Test in Colorectal Cancer

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First step towards reimbursement and adoption of MRD testing in solid tumors

SAN CARLOS, Calif., Aug. 22, 2019/PRNewswire/ -- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced that the Palmetto MolDX program has proposed a local coverage determination (LCD) for use of Natera's Signatera molecular residual disease (MRD) test in patients with certain forms of colorectal cancer (CRC). There are estimated to be 145,600 new CRC diagnoses per year in the U.S., and over 1 million CRC survivors.[1]

The draft LCD proposes coverage for two situations:

1. Patient stratification after surgical resection, where decisions regarding the need for chemotherapy will incorporate the presence or absence of residual disease as determined by Signatera.
2. Recurrence detection in patients with a previous cancer diagnosis but no ongoing clinical evidence of disease. Testing frequency to be in line with current NCCN guidelines on surveillance using carcinoembryonic antigen testing (CEA).

"Patients diagnosed with CRC stand to gain significantly from access to Signatera," said Alexey Aleshin, M.D., M.B.A., Natera's Senior Medical Director of Oncology. "MRD testing can optimize use of adjuvant chemotherapy and detect recurrence at an earlier and possibly curable stage."

The LCD highlights published studies where Signatera MRD status was the only factor significantly associated with relapse-free survival after adjusting for all other standard clinicopathological factors, and where Signatera detected relapse up to 16.5 months earlier (average 8.7 months earlier) than standard diagnostic tools including CT imaging and CEA.[2] It is estimated that the majority of recurrences are currently diagnosed after surgical resection is no longer an option.

"We are very pleased with this proposed LCD," said Solomon Moshkevich, Natera's General Manager of Oncology and Transplant. "Signatera is a breakthrough diagnostic technology, and we look forward to working with Medicare and the oncology community to enable patient access first in colorectal cancer and soon in other cancer types."

The draft LCD is posted here on the Centers for Medicare and Medicaid Services website and is subject to a public comment period before it is finalized.

About Natera
Natera is a global leader in cell-free DNA testing. The mission of the company is to change the management of disease worldwide with a focus on reproductive health, oncology, and organ transplantation. Natera operates an ISO 13485-certified and CAP-accredited laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) in San Carlos, Calif. It offers proprietary genetic testing services to inform physicians who care for pregnant women, 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.

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 designated by the FDA as a Breakthrough Device. The Signatera methodology 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 tissue. 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 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 was developed by Natera, Inc. a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

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, our expectations regarding the reliability, accuracy and performance of our screening tests, or regarding the benefits of our screening tests and product offerings to patients, providers and payers, or our ability to obtain favorable coverage and reimbursement determinations from third-party 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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2. Reinert T, Henriksen T, Christensen E, et al. Analysis of plasma cell-free DNA by ultradeep sequencing in patients with stages I to III colorectal cancer. *JAMA Oncol*. 2019.