Data Presented at ASCO Shows Natera's Signatera Test Detects Immunotherapy Treatment Response in Metastatic Cancers

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Results Support Use of New Blood Test as Surrogate Endpoint in Clinical Trials Assessing Immune Checkpoint Inhibitor Effectiveness

SAN CARLOS, Calif., June 3, 2019 /PRNewswire/ -- A new study demonstrates the ability of Natera's Signatera™ test to assess patient response to immunotherapy in the metastatic setting across multiple cancer types by detecting molecular traces of circulating tumor DNA (ctDNA) in the blood. The study was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on June 1, 2019.

The study, conducted by Princess Margaret Cancer Centre in Toronto, enrolled 70 patients with advanced cancer, including head and neck, triple-negative breast, melanoma, and ovarian cancers. Patients were treated with the single-agent immune checkpoint inhibitor pembrolizumab as part of the phase II INSPIRE trial (NCT02644396). The study used Signatera to assess ctDNA at baseline and again at the start of the third treatment cycle.

Results showed a strong correlation between changes in ctDNA and overall survival (adjusted HR=0.38, p=0.004), progression-free survival (adjusted HR=0.47, p=0.006), and overall clinical response rate, illustrating that ctDNA may be a valuable predictive biomarker for patients with mixed solid tumors treated with checkpoint inhibitors. Signatera, a personalized, tumor-informed blood test, detected ctDNA in 68 out of 70 patients at baseline (97 percent sensitivity).[1]

The study (abstract 2542), titled "Bespoke Circulating Tumor DNA (ctDNA) Analysis as a Predictive Biomarker in Solid Tumor Patients (pts) Treated With Single Agent Pembrolizumab (P)," can be accessed here.

"This study is another strong indication of Signatera's potential to impact the management of cancer, following several other studies recently published in key peer-reviewed journals," said Alexey Aleshin, M.D., MBA, Natera's oncology medical director. "This growing body of evidence highlights the promise of our technology to help physicians and researchers detect molecular residual disease, measure treatment response, and identify recurrence earlier than the standard of care in patients with a variety of cancers."

Across clinical studies in breast, bladder, colorectal, and non-small cell lung cancers, Natera has demonstrated the ability to detect molecular residual disease up to two years earlier than radiographic imaging.[2-6] Results also have shown that a positive Signatera result without further treatment has predicted clinical relapse over 98 percent of the time.[2-6]

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. 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 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 improve prognosis and help optimize treatment decisions.

Natera will also offer a research-use-only service for plasma-based whole exome sequencing to create a personalized assay when tissue is not available, or reflexively for Signatera ctDNA positive cases, to characterize resistance mutations, actionable mutations, neoantigens, and tumor evolution. The service will interrogate approximately 20,000 genes from ctDNA to detect somatic mutations, representing a significant increase in coverage over most commercially available fixed liquid biopsy panels. If ordered as a combined service, researchers can first use Signatera to monitor patients for the presence or absence of ctDNA, and for positive patients they can reflex to a plasma exome to characterize tumor evolution using the same exact DNA library sample. Natera expects the service to become available in the second half of 2019.

About Natera

Natera, Inc. (NASDAQ: NTRA) 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 a host of proprietary genetic testing services to inform physicians who care for pregnant women, researchers in cancer 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, our collaborations with commercial partners such as medical institutions, contract laboratories, laboratory partners, and other third parties, whether the results of clinical studies will support the use of our product offerings, our expectations of the reliability, accuracy and performance of our screening tests, or of the benefits of our screening 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.

This test 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.

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