Natera Announces First Patient Enrollments in Both CIRCULATE-Japan and BESPOKE CRC Trials Using Signatera™ MRD Testing

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Two large-scale studies evaluating use of Signatera in colorectal cancer gain early momentum

SAN CARLOS, Calif., June 18, 2020 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a pioneer and global leader in cell-free DNA testing, today announced that enrollment has begun in the CIRCULATE-Japan and BESPOKE CRC trials, with both studies experiencing strong interest from centers across Japan and the U.S. The studies will measure clinical outcomes of Signatera molecular residual disease (MRD) testing in resectable Stages II-IV colorectal cancer (CRC).

The CIRCULATE-Japan trial, organized by the National Cancer Center (NCC) Japan, is a prospective, multi-center, randomized trial that will investigate optimal circulating tumor DNA (ctDNA)-guided treatment strategies for patients with resectable Stage II-IV CRC, particularly adjuvant chemotherapy decisions based on MRD status. The study will include 2,500 patients from approximately 150 cancer centers across Japan. The NCC's recent announcement on the official launch of the CIRCULATE-Japan trial can be found here.

"We are encouraged to see the trial gaining so much early momentum, and we see a great opportunity ahead to improve treatment decisions for the thousands of CRC patients in Japan, and worldwide, who may not benefit from adjuvant chemotherapy," said the study's Principal Investigator, Dr. Takayuki Yoshino of the NCC Hospital East, Kashiwa-shi, Chiba, Japan. "We are pleased to be working with Natera, whose personalized, tumor-informed ctDNA technology will allow us to more accurately estimate the risk of recurrence after surgery, as well as detect recurrence earlier for novel intervention."

Natera also recently enrolled the first patient in its BESPOKE CRC study, another prospective, multi-center trial that will enroll 1,000 or more patients at time of surgery to measure the clinical impact of serial blood-based testing with Signatera, earlier relapse detection, and better patient risk stratification after surgery. "The breadth of interest in both trials is exceptional. We believe this momentum reflects a clear global unmet need for better recurrence monitoring tools in colorectal cancer and a growing consensus around Signatera's personalized technology as the right diagnostic approach," said Alexey Aleshin, M.D., M.B.A., Natera's Senior Medical Director of Oncology.

In addition to the multiple published studies featuring Signatera technology, the strength of Signatera's personalized approach was on recent display at the American Society of Clinical Oncology (ASCO) 2020 virtual meeting, where Natera and its partners presented the first large, real-world study using personalized MRD in 535 unique patients with Stage I-IV CRC, which is also one of the first studies to evaluate ctDNA detection rates in late stage oligometastatic CRC. The study found that ctDNA detection was significantly associated with stage of disease, with a detection rate of 100% in patients with metastatic and oligometastatic disease, prior to surgery. The study shows the potential utility of Signatera after resection of oligometastatic disease, representing approximately 20-30% of all metastatic CRC patients.[1-3]

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 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. Medicare has proposed insurance coverage for the use of Signatera in patients with Stage II or III colorectal cancer, and it is expected to finalize that coverage decision in mid-2020. Signatera has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA is exercising enforcement discretion of premarket review and other FDA legal requirements for laboratory-developed tests in the US, 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, whether the results of clinical or other studies will support the use of our 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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