Natera Launches Quantification Technique to Enhance Prospera™ Test Precision; Initiates PEDAL Study for New Insights

June 1, 2020

Quantifying background cfDNA increases accuracy of dd-cfDNA testing

SAN CARLOS, Calif., June 1, 2020 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a pioneer and global leader in cell-free DNA testing, is pleased to announce the launch of a novel technique to enhance results from the Prospera donor-derived cell-free DNA (dd-cfDNA) transplant rejection assessment test, as well as a multi-site prospective study to externally validate an enhanced algorithm across multiple clinical indications. The PEDAL Study (Prospera Test Enhancement by Detecting Background Cell-Free DNA Levels) will include 500 kidney transplant patients from 20 major U.S. centers.

Natera has processed more than two million cfDNA tests and leveraged its extensive dataset to conclude that elevated background cfDNA can result in artificially lower dd-cfDNA percentages. Based on its research, Natera now can quantify background cfDNA to more accurately identify those at risk of active rejection. The technique is performed routinely with the Prospera test in a single workflow, without increasing cost or lengthening run time. Details were presented at the American Transplant Congress (ATC), along with data for each of the major factors that impact the levels of background cfDNA. Several case studies of the technique are presented at ATC by leading physicians in the field.

"Natera is the first commercial laboratory to introduce this novel technique. We're pleased to leverage our scientific expertise in cfDNA to improve transplant rejection testing," said Steve Chapman, Natera's CEO. "This innovation further separates the Prospera test from first generation dd-cfDNA tests."

The PEDAL Study will measure the performance of the Prospera test which measures dd-cfDNA and, most recently, background cfDNA. The three key objectives of the study involve: (1) further assessing the performance of the assay to detect rejection, (2) assessing the prognostic ability of cfDNA at the time of biopsy, and (3) assessing the performance of the assay to detect clearance of rejection after treatment. "The PEDAL Study will give us deeper insight into the Prospera test's diagnostic capability and expand the clinical utility of dd-cfDNA testing," said Phil Gauthier, M.D., Natera's medical director of transplant. "We're very pleased to be working with premier physician researchers at top transplant centers across the country, and look forward to beginning enrollment soon."

About the Prospera dd-cfDNA Organ Transplant Test

The Prospera test leverages Natera's core single-nucleotide-polymorphism (SNP)-based massively multiplexed PCR (mmPCR) technology to identify allograft rejection non-invasively and with high precision and accuracy, without the need for prior donor or recipient genotyping. The test works by measuring the fraction of donor-derived cell-free DNA (dd-cfDNA) in the recipient's blood. It may be used by physicians considering the diagnosis of active rejection, helping to rule in or out this condition when evaluating the need for diagnostic testing or the results of an invasive biopsy. The Prospera test has been clinically and analytically validated for performance regardless of donor relatedness, rejection type, and clinical presentation. The Prospera test has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The Prospera 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

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 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 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.

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