FDA Grants Two New Breakthrough Device Designations for Natera's Signatera™ MRD Test

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Designations help accelerate the regulatory review and approval of Signatera across a variety of solid tumor indications

AUSTIN, Texas, March 24, 2021 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a pioneer and global leader in cell-free DNA testing, today announced that the US Food and Drug Administration (FDA) has granted two Breakthrough Device Designations (BDDs) covering new intended uses of the Signatera molecular residual disease (MRD) test. These new designations will support the development of Signatera through Phase III clinical trials as a companion diagnostic to two different cancer therapies. Together with the BDD granted to Signatera in 2019, this makes a total of three BDDs granted across multiple cancer types and indications.

These new designations reflect the increasing momentum Natera has seen in its oncology biopharma business, with over $65M in contracts signed over the past year including multiple Phase III registrational trials that incorporate Signatera as a companion diagnostic. They also reflect the significant investments that Natera has made in regulatory affairs and quality systems to support precision oncology.

"We are committed to working with the FDA and with our biopharma partners to validate the use of the Signatera MRD test across a broad range of solid tumor indications," said Fayyaz Memon, Vice President of Regulatory Affairs at Natera. "These two new Breakthrough Device Designations will help us accelerate our mission to bring life-saving diagnosis and treatment to cancer patients as early as possible."

Under the BDD program, the FDA helps accelerate the approval of novel technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases. A recent policy proposed by the Centers for Medicare and Medicaid Services (CMS) would also, if finalized, provide an accelerated path to reimbursement for Breakthrough Devices that are FDA cleared or approved.

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 both clinical and research use, and has been granted three Breakthrough Device Designations by the FDA for multiple cancer types and indications. 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. Signatera 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 Austin, Texas and San Carlos, California. 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 collaborations with commercial partners such as pharmaceutical companies, medical institutions, contract laboratories, laboratory partners, and other third parties, 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 https://investor.natera.com and www.sec.gov.

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