Natera Obtains Z-Codes for Signatera MRD and Treatment Monitoring Test in Oncology

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Represents Key Reimbursement Milestone In Line with Planned Clinical Launch

SAN CARLOS, Calif., Jan. 4, 2019 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a global leader in non-invasive genetic testing and cell-free DNA, today announced the assignment of two Z-codes for the company's Signatera™ test, in preparation for its planned clinical launch in Q2 2019. Signatera, when clinically available, is intended for use by oncologists to detect molecular residual disease (MRD) and monitor treatment response in cancer patients.

Two Z-codes were awarded, ZB8DC and ZB8DD, representing the initial and subsequent test orders for each patient. These codes will cover multiple cancer types, as the Signatera technology has shown consistent performance across multiple cancers, including lung, breast, colorectal, and bladder.

"The attainment of these Z-codes is an essential part of our reimbursement strategy and is in line with our planned clinical launch this year," said Solomon Moshkevich, Natera's General Manager, Oncology and Transplant Businesses. "When it is launched, we expect that Signatera will become a powerful new tool in the oncologist's arsenal for post-treatment MRD assessment, treatment response monitoring, and earlier detection of recurrence."

About Signatera™

Signatera is the first ctDNA assay custom-built for treatment monitoring and MRD assessment. The test is currently available for Research Use Only (RUO), until its clinical launch currently planned for Q2 2019. The Signatera methodology differs from currently available liquid biopsy assays, which test for a fixed panel of therapeutically relevant genes. Signatera provides each individual with a customized blood test tailored to match the clonal mutations found in that individual's tumor tissue. This maximizes accuracy for detecting the presence or absence of MRD in a blood sample, even at levels down to a single mutant molecule in a tube of blood. Signatera RUO also allows researchers to track additional mutations of interest, up to several hundred mutations, for clinical studies.

The body of evidence on the utility of Signatera is growing. A 2017 study demonstrated the Signatera RUO method's ability to detect MRD, measure treatment response, and identify recurrence up to 11 months earlier than the standard of care for early stage non-small cell lung cancer (NSCLC) with 93 percent sensitivity and zero false positives. Additional research presented at the European Society for Medical Oncology 2018 Congress showed successful results from bladder and colorectal cancer studies, including median detection points of ctDNA that were 3.3 and 7.9 months, respectively, ahead of clinical relapse detection. In two studies presented at the 2018 San Antonio Breast Cancer Symposium (SABCS), Signatera RUO was able to detect MRD up to two years prior to clinical relapse and to predict treatment response in a cross-section of breast cancer patients, including those who were HER-2 positive, hormone receptor-positive and triple negative. Based on numerous studies across multiple cancer types, a positive Signatera RUO result without further treatment has predicted clinical relapse nearly 100% of the time.

About Natera

Natera is a global leader in cell-free DNA testing. The mission of the company is to transform the management of diseases worldwide. 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 bio pharmaceutical companies, and genetic laboratories through its cloud-based software platform. For more information, visit natera.com. Follow Natera on LinkedIn and Twitter.

Forward-Looking Statements

All statements other than statements of historical facts, including the quotations of management, 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.

Contacts

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