Natera Presents Breast Cancer Data at SABCS Showing Ability of Signatera (RUO) to Detect Molecular Residual Disease Up to Two Years Prior to Clinical Relapse and Predict Treatment Response

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Study Demonstrates Utility of Assay in Neoadjuvant and Adjuvant Treatment Settings

SAN CARLOS, Calif., Dec. 6, 2018 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a leader in non-invasive genetic testing and the analysis of cell-free DNA, presented data from two studies this week at the 2018 San Antonio Breast Cancer Symposium (SABCS), demonstrating the ability of its Signatera™ RUO (research-use-only) circulating tumor DNA (ctDNA) assay to detect molecular residual disease (MRD) up to two years prior to clinical relapse and to predict treatment response in breast cancer.

Both breast cancer studies included a cross-section of patient subtypes, including HER2-positive, hormone receptor-positive, and triple-negative.

- **I-SPY 2 study**: In a cohort of 82 high-risk early-stage breast cancer patients receiving neoadjuvant therapy, the change of measurable ctDNA from positive to negative during neoadjuvant treatment predicted therapeutic response, while failure to clear ctDNA after neoadjuvant treatment correlated with poor clinical outcomes (p<0.001). ctDNA levels were also associated with tumor burden as determined by imaging (p<0.01). Abstract 1259: Personalized serial circulating tumor DNA (ctDNA) analysis in high-risk early stage breast cancer patients to monitor and predict response to neoadjuvant therapy and outcome in the I-SPY 2 TRIAL.

- **Leicester/Imperial study**: In a cohort of 49 breast cancer patients who received adjuvant therapy, Signatera (RUO) detected molecular residual disease with a lead time of up to two years prior to clinical or radiological detection (median 8.9** months; range 0.5–24.0 months). Overall, Signatera (RUO) detected clinical relapse with a sensitivity of 89 percent and specificity of 100 percent. Abstract 1266: Early detection of residual breast cancer through a robust, scalable and personalized analysis of circulating tumour DNA (ctDNA) antedates overt metastatic recurrence.

"Our outstanding performance using Signatera (RUO) in clinical studies to detect molecular residual disease and monitor treatment response across lung, bladder, and colon cancers continues in breast cancer," said Jimmy Lin, M.D., Ph.D., MHS, Natera's Chief Scientific Officer, Oncology. "We look forward to sharing this new data and discussing the implications for using Signatera more broadly in clinical trials for patient selection, prognostic evaluation, treatment response monitoring, and recurrence monitoring in the neoadjuvant, adjuvant, and metastatic settings."

"The consistently strong performance of this assay demonstrates that our unique approach is realizing the promise of personalized medicine in local-regionally advanced early-stage cancer management," said Alexey Aleshin, M.D., Oncology Medical Director, Natera. "The body of evidence is building, and we are excited to see these new results in breast cancer. This represents a key milestone in making our assay available for clinical practice and for use in novel neoadjuvant and adjuvant clinical trial designs."

About Signatera (Research-Use-Only)

Signatera (RUO) is the first ctDNA assay custom-built for treatment monitoring and molecular residual disease assessment. The Signatera (RUO) methodology differs from currently available liquid biopsy assays, which test for a panel of genes independent of an individual's tumor. Signatera (RUO) provides each patient with a customized blood test tailored to match the mutations found in that individual's tumor tissue, which maximizes sensitivity and specificity. 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 molecular residual disease, 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.

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 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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“I-SPY 2 TRIAL stands for “Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2” (NCT01042379). The goal is to identify improved treatment regimens for subsets of patients on the basis of molecular characteristics (biomarker signatures) of their disease. New drugs enter the trial as those that have undergone testing complete their evaluation. Quantum Leap Healthcare Collaborative (QLHC) is the sponsor of the I-SPY 2 TRIAL, and is a 501C(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY; www.quantumleaphealth.org

**Abstract data updated after publication.

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