

NEWS RELEASE

Natera to Partner with AMAL Therapeutics on Clinical Trial Using Signatera MRD Test to Assess Treatment Response to Colorectal Cancer Vaccine

New Clinical Trial Adds to Growing Number of Studies Supporting Use of Signatera as a Potential Surrogate Endpoint

SAN CARLOS, Calif., March 26, 2019–<u>Natera, Inc.</u> (NASDAQ: NTRA), a global leader in cell-free DNA testing, will partner with AMAL Therapeutics on a clinical trial focused on stage IV colorectal cancer. This study adds to the growing number of pharmaceutical trials using Natera's Signatera[™] molecular residual disease (MRD) assay as a biomarker to assess treatment response.

The AMAL Therapeutics prospective clinical trial, referred to as KISIMA[®]-01, will assess the safety, tolerability, and preliminary efficacy of ATP128, the company's leading therapeutic cancer vaccine, in combination with a PD1 blockade in defined patient populations with stage IV colorectal cancer. The Signatera test will be used as a biomarker to evaluate treatment response. The test is custom-designed to each patient's tumor profile, a personalized approach that is well positioned to measure treatment response to this first-in-class therapeutic vaccine in the patient population eligible for surgery.

"This trial is meaningful for us, not only because it addresses a patient population that often has a poor prognosis, but also because it demonstrates the continued adoption of Signatera for use as a potential surrogate endpoint in clinical trials to evaluate treatment response and predict outcomes across a wide range of solid tumors," said Alexey Aleshin, M.D., M.B.A., Natera's oncology medical director. "We are excited to collaborate with AMAL Therapeutics on the development of its first asset designed from the KISIMA vaccine technology platform."

"Signatera is gaining momentum, and we now have more than 30 trials underway with pharmaceutical companies. There's significant interest in using Signatera to monitor treatment response and also as a molecular residual disease biomarker for study enrichment across a variety of cancer types, novel therapies, and vaccines," said Steve Chapman, Natera's CEO.

About Signatera[™]

<u>Signatera</u> is the first circulating tumor DNA (ctDNA) test custom-built for molecular treatment monitoring and molecular residual disease (MRD) assessment. The test is available for research use only (RUO) until its clinical launch planned for Q2 2019. The Signatera methodology differs from currently available liquid biopsy tests, 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 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.¹
- Data presented at the European Society for Medical Oncology 2018 Congress showed successful results from bladder and colorectal cancer studies, including median detection points of MRD that were 3.3 and 7.9 months, respectively, ahead of clinical relapse detection.^{2,3}
- In two studies presented at the 2018 San Antonio Breast Cancer Symposium, Signatera RUO was able to detect MRD up to two years prior to clinical relapse and predict treatment response in a cross-section of breast cancer patients, including those who were HER-2 positive, hormone receptor-positive, and triple negative.^{4,5}

Based on numerous studies across multiple cancer types, a positive Signatera RUO result, without further treatment, has predicted clinical relapse over 98 percent of the time.¹⁻⁵

About Natera

<u>Natera</u> is a global leader in cell-free DNA testing. The mission of the company is to change the management of disease 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, kidney transplant recipients, cancer researchers including biopharmaceutical companies, and genetic laboratories through its cloud-based software platform.

Natera 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, our collaborations with commercial partners such as medical institutions, contract laboratories, laboratory partners, and other third parties, 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 <u>www.natera.com/investors</u> and <u>www.sec.gov</u>.

Contacts for Natera

Investor Relations: Mike Brophy, CFO, Natera, Inc., 650-249-9090 Media: Andrea Sampson, Sullivan & Associates, 714-374-6174, <u>asampson@sullivanpr.com</u>

References

- 1. Abbosh C, Birkbak NJ, Wilson GA, et al. Phylogenetic ctDNA analysis depicts early-stage lung cancer evolution. Nature. 2017; 545(7655):446–451.
- Reinert T, Henriksen TV, Rasmussen MH, et al. Serial Circulating Tumor DNA Analysis for Detection of Residual Disease, Assessment of Adjuvant Therapy Efficacy and for Early Recurrence Detection in Colorectal Cancer. Poster presented at: European Society for Medical Oncology Annual Congress; October 21, 2018; Munich, Germany. Abstract 456PD.
- 3. Birkenkamp-Demtröder K, Christensen E, Sethi H, et al. Sequencing of Plasma cfDNA from Patients with Locally Advanced Bladder Cancer for Surveillance and Therapeutic Efficacy Monitoring. Poster presented at: European Society for Medical Oncology Annual Congress; October 20, 2018; Munich, Germany. Abstract 86P.
- 4. Magbanua M, Brown-Swigart L, Hirst G, et al. 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. Data presented at spotlight session: San Antonio Breast Conference Symposium; December 5, 2018. Abstract 1259.
- Coombes RC, Armstrong A, Ahmed S, Page K, et al. Early detection of residual breast cancer through a robust, scalable and personalized analysis of circulating tumour DNA (ctDNA) antedates overt metastatic recurrence. Poster presented at: San Antonio Breast Conference Symposium; December 7, 2018. Abstract 1266.