



NEWS RELEASE

Natera Announces Expanded I-SPY 2 Collaboration to Evaluate Signatera™ for Breast Cancer Patients in the Neoadjuvant Setting

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Prospective study to monitor 600 patients in real time, across all subtypes of breast cancer

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced a new study as part of the I-SPY 2 trial, sponsored and operated by Quantum Leap Healthcare Collaborative, that will use Signatera, Natera's personalized and tumor-informed molecular residual disease (MRD) test, to monitor response to neoadjuvant therapy in breast cancer patients across all subtypes.

This prospective study, in which 600 patients will be monitored in real time, will support efforts to establish circulating tumor DNA (ctDNA) as a composite endpoint and generate additional data on post-surgical ctDNA status in patients treated with neoadjuvant therapy. It expands on the existing collaboration with the I-SPY-2 consortium that has led to the publication of multiple studies validating the use of Signatera for neoadjuvant response monitoring and predicting recurrence risk, including studies published in *Cancer Cell*¹ and *Annals of Oncology*.²

"We are excited to expand our collaboration and help generate a large, prospective dataset to support the incorporation of ctDNA testing into future interventional trials in neoadjuvant breast cancer treatment," said Laura Esserman, MD, MBA, and Laura van 't Veer, PhD, professors at the University of California, San Francisco, and principal investigators of the I-SPY study. "We believe this study, in combination with our prior work in I-SPY 2, will help us understand the role that ctDNA can play in decision making for predicting response and improving our ability to determine who needs less therapy and who needs more. This is of utmost importance to patients."



“There is a significant unmet need for more accurate tools to enable precision care for patients diagnosed with breast cancer,” said Minetta Liu, MD, chief medical officer of oncology at Natera. “I-SPY 2 serves as an excellent platform to investigate Signatera’s utility in the neoadjuvant and adjuvant settings. This extended collaboration will enhance our understanding of Signatera’s ability to assess therapy response, predict clinical outcomes, and advance a more personalized treatment strategy for patients with breast cancer.”

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 four 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. Signatera is intended to detect and quantify cancer left in the body, at levels down to a single tumor molecule in a tube of blood, to identify recurrence earlier and to help optimize treatment decisions. The test has not been cleared or approved by the US Food and Drug Administration (FDA).

About Natera

Natera™ is a global leader in cell-free DNA testing, dedicated to oncology, women’s health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard of care to protect health, and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera’s tests are validated by more than 150 peer-reviewed publications that demonstrate high accuracy. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas and San Carlos, California. For more information, visit www.natera.com.

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 whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, 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 www.natera.com/investors and www.sec.gov.

References:

1. Magbanua MJM, Swigart LB, Ahmed Z, et al. Clinical significance and biology of circulating tumor DNA in high-risk early-stage HER2-negative breast cancer receiving neoadjuvant chemotherapy. *Cancer Cell*. 2023;41(6):1091-1102.
2. Magbanua MJM, Swigart LB, Wu H-T, et al. Circulating tumor DNA in neoadjuvant-treated breast cancer reflects response and survival. *Ann Oncol*. 2021;32(2):229-239.

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