



NEWS RELEASE

Natera Presents New Signatera™ MRD Data Across Breast Cancer Treatment Settings at SABCS 2023

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Includes new data from prospective clinical trials in HR+/HER2- breast cancer evaluating treatment on molecular recurrence (TOMR) and additional real-world data across all breast cancer subtypes

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced new data being presented on its personalized and tumor-informed molecular residual disease (MRD) test, Signatera, at the 2023 San Antonio Breast Cancer Symposium (SABCS) in San Antonio, Texas.

Natera and its collaborators are presenting two poster spotlight discussions and three posters. The presentations feature tumor-informed MRD data spanning the neoadjuvant, adjuvant, surveillance, and metastatic treatment settings, including analyses from the DARE, monarchE, and LEADER trials in HR+/HER2- breast cancer.

"We are excited to showcase our leadership at SABCS with thought-provoking new data that demonstrate our commitment to personalizing patient care across the breast cancer continuum," said Minetta Liu, MD, chief medical officer of oncology, at Natera. "We are highly encouraged by the excellent preliminary findings from prospective, interventional clinical trials such as DARE and LEADER, which we believe will further demonstrate the utility of treatment on molecular recurrence with Signatera."

[Highlights from selected abstracts include:](#)

PS06-02 | Poster Spotlight Discussion | DARE Study | HR+/HER2- Surveillance (TOMR) |
Presenter: Lajos Pusztai, MD

Circulating tumor DNA (ctDNA) monitoring of estrogen receptor-positive, human epidermal growth factor receptor

2-negative (ER+/HER2-) high risk breast cancer during adjuvant endocrine therapy

DARE is a first-of-its-kind, multi-center, prospective, randomized clinical trial, which was first announced in October 2020. An interim readout of over 400 patients prescreened for ctDNA detection and enrollment in the interventional trial demonstrates that ~9% of patients tested ctDNA-positive with a median screening time of 13.4 months per patient. Over 70% of patients experienced molecular-only relapse (i.e. ctDNA positivity with no evidence of metastatic disease on imaging), which is the highest rate seen in a prospective study to date and demonstrates the feasibility of TOMR study designs in breast cancer. These patients were successfully randomized to receive endocrine therapy in combination with palbociclib vs. continuing standard of care. Initial ctDNA dynamics were presented, including clearance events. The association of this data with treatment benefit will be presented at future meetings.

PS06-01 | Poster Spotlight Discussion | monarchE Study | HR+/HER2- Surveillance (adjuvant CDK4/6i) | Presenter: Stephanie Graff, MD, FACP

Results from a study exploring ctDNA detection in the monarchE trial of adjuvant abemaciclib with endocrine therapy in HR+, HER2-, node-positive, high-risk early breast cancer

This study investigated the technical feasibility of ctDNA testing beginning prior to adjuvant CDK4/6i therapy and examined rates of ctDNA persistence and clearance in a highly selected cohort of 178 patients from the phase 3 monarchE trial, which excluded any recurrences in the first 24 months after surgery. Persistent ctDNA positivity during two years of treatment was found to be associated with a 100% risk of relapse. Additionally, none of the patients developed recurrence if they were initially ctDNA-positive and later became ctDNA-negative during treatment (ctDNA clearance). An analysis of an expanded cohort is ongoing, which will be more reflective of the intent-to-treat population and will include additional time points and recurrent cases within the 2-year treatment period.

Below are additional Natera abstracts being presented at SABCS:

- PO3-13-09 | Poster Session 3 | LEADER Study | HR+/HER2- Surveillance (TOMR) | Presenter: Arielle Medford, MD
Personalized ctDNA testing for detection of MRD in patients with localized HR+ breast cancer: temporal dynamics and impact on clinical outcomes.
- PO4-15-12 | Poster Session 4 | Neoadjuvant Treatment Monitoring (all subtypes) | Presenter: Mridula George, MD
Personalized ctDNA monitoring to predict response to neoadjuvant therapy in patients with early-stage breast cancer
- PO5-13-12 | Poster Session 5 | Metastatic Invasive Lobular Carcinoma (mILC) Treatment Monitoring (all

subtypes) | Presenter: Steffi Oesterreich, PhD

Personalized ctDNA testing for recurrence detection and treatment response monitoring in patients with mILC

All abstracts can be found on the SABCS website [here](#).

About Signatera

Signatera is a personalized, tumor-informed, molecular residual disease test for patients previously diagnosed with cancer. Custom-built for each individual, Signatera uses circulating tumor DNA to detect and quantify cancer left in the body, identify recurrence earlier than standard of care tools, and help optimize treatment decisions. The test is available for clinical and research use and is covered by Medicare for patients with colorectal cancer, breast cancer (stage IIb and higher) and muscle invasive bladder cancer, as well as for immunotherapy monitoring of any solid tumor. Signatera has been clinically validated across multiple cancer types and indications, with published evidence in more than 50 peer-reviewed papers.

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.

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