



NEWS RELEASE

# Natera Announces Three New Signatera Publications; Includes Groundbreaking Overall Survival Data Published in Nature Medicine and also Released at ESMO

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Signatera now has >85 peer-reviewed publications with clinical validation across multiple cancer types and indications

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and genetic testing, today announced the simultaneous publication of three peer-reviewed papers, crossing a milestone of more than 85 peer-reviewed publications on Signatera. This includes:

- Groundbreaking colorectal cancer (CRC) data from the GALAXY arm of the ongoing CIRCULATE-Japan trial, **published today in Nature Medicine** , and also available in Poster Presentation #553P at the 2024 Congress of the European Society for Medical Oncology (ESMO) in Barcelona, Spain.
- Additional CRC data from GALAXY, **published today in Annals of Oncology** , and also available in Poster Presentation #558P at ESMO.
- A new paper from the BELLINI trial, **published today in Nature Medicine** , investigating the feasibility and potential efficacy of immune checkpoint inhibitors (ICI) without concurrent chemotherapy in triple negative breast cancer (TNBC).

## [CRC Data from GALAXY \( Nature Medicine & ESMO Poster\)](#)

In this study, 2,240 patients with stage II- IV CRC were monitored using Signatera after curative-intent surgery with



a median follow-up of 23 months. This data provides the first evidence of Signatera-based molecular residual disease (MRD) detection to predict overall survival (OS) and highlights Signatera's ability to predict adjuvant chemotherapy (ACT) benefit. Full details on the data are available [here](#), as announced on Sept. 14, 2024.

### CRC Data from GALAXY ( Annals of Oncology & ESMO Poster)

This study retrospectively analyzed 190 patients enrolled in GALAXY who underwent surgical resection for colorectal liver metastases and underscores Signatera's ability to risk-stratify CRC patients. Of the patients who were Signatera-positive within 2-10 weeks after surgical resection, 24-month disease free survival (DFS) was superior for those who received ACT compared to patients on observation, whereas no statistically significant benefit of ACT was observed among Signatera-negative patients.

### Breast Cancer Data from Bellini Trial ( Nature Medicine )

This study reports initial results from the BELLINI trial, a phase 2 study that enrolled 43 patients with stage I-III triple-negative breast cancer (TNBC). Patients in the study underwent short-term (2-3 cycles) of nivolumab, alone or in combination with ipilimumab, prior to standard-of-care neoadjuvant chemotherapy or surgery. Circulating tumor DNA (ctDNA) analysis with Signatera was performed before treatment and after 4 or 6 weeks of treatment. All clinical responders including patients who achieved pathologic complete response demonstrated at least a 50% decrease in ctDNA levels, or were ctDNA-negative at baseline.

"We are extremely proud to announce the publication of these datasets in top-tier medical journals, underscoring the breadth of clinical evidence we continue to build on the utility of Signatera," said Alexey Aleshin, MD, MBA, general manager of oncology and chief medical officer of Natera. "The first overall survival readout in colorectal cancer from GALAXY marks a landmark moment that may fundamentally change how resectable colorectal cancer is managed for the hundreds of thousands of patients at risk of recurrence each year. We are especially grateful to the patients who participated in these trials, as well as our collaborators and study investigators for their dedication to improving outcomes for patients."

## 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, ovarian cancer 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 85 peer-reviewed papers.

## About Natera

Natera™ is a global leader in cell-free DNA and genetic 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 200 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](http://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](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov) .

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