



NEWS RELEASE

# Natera Announces Successful Readout of Randomized, Phase III CALGB (Alliance) / SWOG 80702 Clinical Trial in Colorectal Cancer

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Readout of ~1K patients at ASCO GI 2025 demonstrates that Signatera™ positive patients treated with both chemotherapy and celecoxib had a 40% improvement in overall survival versus chemotherapy alone

Additional ASCO GI poster highlights data from the ALTAIR clinical trial, showing significant clinical benefit in patients with stage IV colorectal cancer who were treated with Trifluridine/Tipiracil (FTD/TPI)

AUSTIN, Texas,--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and genetic testing, announced new data from the randomized, Phase III CALGB (Alliance) / SWOG 80702 study. The study will be presented today, Jan. 25, 2025 as a late-breaking oral presentation at the 2025 American Society of Clinical Oncology's Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco, CA.

This first-of-its-kind study evaluated whether Signatera-positive patients benefit from an escalation in adjuvant treatment. In the trial, Signatera was used to evaluate the benefit of adding celecoxib, a non-steroidal anti-inflammatory drug (NSAID), to standard of care (SOC) adjuvant chemotherapy with FOLFOX in the management of stage III colorectal cancer (CRC). The pre-specified analysis included approximately 1,000 patients with available post-surgical plasma samples, who were randomized to receive FOLFOX (+/-) celecoxib.

Key findings included:

- Signatera-positivity after surgery was predictive of a disease-free survival (DFS) and overall survival (OS)



benefit with the addition of celecoxib to adjuvant FOLFOX. The addition of celecoxib to SOC chemotherapy significantly improved DFS compared to placebo (HR 0.55, 95% CI 0.39-0.80; p=0.001) among Signatera-positive patients with a three-year DFS of 44.1% versus 26.6%. Similar results were seen for OS (HR 0.58, 95% CI 0.38-0.90; p=0.013). No survival benefit was seen by adding celecoxib to chemotherapy in Signatera-negative patients.

- Signatera status after surgery and prior to starting adjuvant therapy was highly predictive of recurrence. Signatera-positivity was significantly associated with worse DFS (HR 7.14, 95% CI: 5.54-9.21; p<0.0001) and OS (HR 6.72, 95% CI: 4.91-9.18; p<0.0001).

“The results from the CALGB (Alliance) / SWOG 80702 study mark an unprecedented moment in personalized medicine for patients with colorectal cancer,” said Alexey Aleshin, M.D., corporate chief medical officer and general manager of oncology for Natera. “We demonstrated Signatera’s ability to predict a benefit in both disease-free survival and overall survival for Signatera-positive patients from the addition of celecoxib, an extremely accessible, affordable, and well-tolerated therapy. These data also offer compelling evidence to address an unmet need in adjuvant colorectal cancer treatment, where there has not been a new drug approval in over 20 years.”

The results of the randomized, double-blind ALTAIR clinical trial will also be presented in a poster today. ALTAIR examined treatment escalation with Trifluridine/Tipiracil (FTD/TPI) in patients with stage I-IV colorectal cancer. In the trial, 243 Signatera-positive patients were randomized to FTD/TPI or placebo over a six-month treatment period. The results showed a trend toward benefit in the FTD/TPI group (median DFS of 9.3 months vs. 5.6 months in the placebo group), although it did not reach statistical significance (HR, 0.79; P = 0.107). There was a significant benefit for resected oligometastatic stage IV patients treated with FTD/TPI, showing a median DFS of 9.76 months as compared to 3.96 months in the placebo group (HR, 0.53; P = 0.012). This presents an opportunity for clinical benefit in stage IV patients who test positive for MRD.

## 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 over 100 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 250 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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