NEWS RELEASE

Natera Reports Strong Advanced Adenoma Data from Prospective PROCEED-CRC Trial, Demonstrating 22.5% Sensitivity and 91.5% Specificity

2025-10-28

Findings underscore strength of Natera's technology for early cancer detection (ECD)

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced another successful readout for its ECD program, which is evaluating a blood-based screening test for the detection of CRC and advanced adenomas (AA). This latest analysis from the U.S. based, prospective PROCEED-CRC clinical trial (NCT06620627) focused on the detection of AAs, which are precancerous polyps with specific features that indicate a higher risk of progression to colorectal cancer. Detecting these lesions early is a critical step in preventing cancer before it develops.

PROCEED-CRC has enrolled approximately 5,000 average-risk asymptomatic screening participants with blood draws taken pre-colonoscopy. This analysis started with approximately 1,400 PROCEED-CRC cases that were collected prior to the cutoff date, incorporating 92 sequentially collected AA samples and a representative cohort of 366 normal controls. The study showed sensitivity of 22.5% (CI: 15.4%-32.4%) and specificity of 91.5% (CI: 88.2%-93.9%) and encompassed all histologic subtypes, including serrated polyps. When adjusted for subtype prevalences found in two recent CRC screening FDA-enabling trials1,2, sensitivity was 22.4% and 23.7%. Additionally, in this study, 98.9% of AA cases were less than 30 millimeters and 93.5% were below 20 millimeters, which represents a challenging size distribution because smaller lesions can be more difficult to detect.

Earlier in 2025, Natera reported preliminary AA performance data from a pilot study with 18% sensitivity and 91% specificity. Since that time, several technology changes have resulted in improved assay performance. These

findings create increased confidence going into the FIND clinical trial (NCT07046585), an FDA-grade validation study, which was initiated in 2025 and continues to make significant progress.

“This data represents another important milestone in our efforts to advance blood-based colorectal cancer screening,” said Alexey Aleshin, M.D., general manager of oncology and early cancer detection, and chief medical officer at Natera. “Detecting advanced adenomas is critical for intercepting colorectal cancer before it develops, and this exceptional performance highlights the strong potential of our technology to transform early detection.”

These results build on previously reported case-control data from screen-detected CRC cases, which were also **announced** earlier this year showing overall sensitivity of 95% (95% CI: 92-99%) and specificity of 91% (95% CI: 88-94%). Among patients with stage I disease, sensitivity was 92% overall. Stage-adjusted sensitivity was 91% in screen-detected individuals.

References

1. Chung D.C. et al.A cell-free DNA blood-based test for colorectal cancer screening.N Engl J Med. 2024;390(11):973-983. doi: **10.1056/NEJMoa2304714**
2. Shaukat A. et al.Clinical validation of a circulating tumor DNA-based blood test to screen for colorectal cancer.JAMA. 2025;334(1):56-63. doi: **10.1001/jama.2025.7515**

About Natera

Natera™ is a global leader in cell-free DNA and precision medicine, 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 supported by more than 300 peer-reviewed publications that demonstrate excellent performance. 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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Source: Natera, Inc.