



NEWS RELEASE

# Natera Submits First PMA Module to the FDA for Signatera™

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Lays groundwork for multiple submissions across cancer types, starting with CDx label in bladder cancer

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced the submission of the first module of its premarket approval (PMA) application to the U.S. Food and Drug Administration (FDA) for Signatera, Natera's personalized and tumor-informed molecular residual disease (MRD) test, as a companion diagnostic (CDx) assay for patients with muscle-invasive bladder cancer (MIBC).

This module, submitted on September 28, included the required documentation regarding Natera's manufacturing and quality control systems, which the Company expects will support all future indications for Signatera as well as other Natera products. The remaining modules for the Signatera MIBC indication, including software, analytical and clinical validation data, are expected to be submitted through 2025 upon completion of the ongoing registrational trial.

"With this initial step towards a PMA for Signatera, we are continuing to build on our longstanding engagement with the FDA," said Steve Chapman, chief executive officer of Natera. "This milestone reflects the significant efforts of our team in developing an FDA-grade quality and manufacturing system, a strong foundation designed to support future regulatory submissions across disease indications for Signatera and across product lines."

Signatera has previously been granted four Breakthrough Device Designations by the FDA, including the CDx claim in MIBC submitted in the PMA module package.

[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 help identify recurrence earlier and 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](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 our efforts to develop and commercialize our product offerings, 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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