



NEWS RELEASE

FDA Grants Breakthrough Device Designation for Natera's Multi-Cancer Early Detection Assay

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Designation supports the development of a blood-based assay intended to screen for various cancers

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced that its multi-cancer early detection (MCED) assay has been granted Breakthrough Device designation (BDD) by the U.S. Food and Drug Administration (FDA). The BDD is designed for novel technologies that enable more effective diagnosis or treatment of life-threatening or irreversibly debilitating diseases or conditions.

Natera's MCED assay analyzes cell-free DNA in the blood to screen for multiple cancers. In granting the BDD, the FDA assessed data from 12 cancer types and considered sensitivity, specificity, and cancer signal origin (CSO) performance. The test generated compelling results to support the designation.

"Too many cancers are diagnosed after they've progressed, simply because limited screening options exist," said Alexey Aleshin, M.D., corporate chief medical officer and general manager, oncology and early cancer detection, Natera. "This designation underscores the rigor and promise of our MCED program, and we look forward to working with the FDA as we aim to detect cancer earlier, when it's easier to treat."

The Breakthrough Devices program is intended to provide patients and healthcare providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization. Devices must meet rigorous criteria to earn the designation.

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 400 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, and through Foresight Diagnostics, its subsidiary, operates an ISO 27001-certified and CAP-accredited laboratory certified under CLIA in Boulder, Colorado. 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 our efforts to develop and commercialize new product offerings, 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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