NEWS RELEASE

Foundation Medicine and Natera Announce the Launch of FoundationOne®Tracker Personalized Circulating Tumor DNA Monitoring Assay for Investigational Use and Early Access Clinical Use

1/9/2023

FoundationOne®Tracker provides physicians and researchers with a tissue-informed and personalized solution to monitor advanced cancer patients' response to treatment, and help optimize future treatment decisions and therapy development

Cambridge, Mass., & Austin, Texas, January 9, 2023 – **Foundation Medicine, Inc.**, a pioneer in molecular profiling for cancer, and Natera, Inc., a global leader in cell-free DNA testing, today launched an early access program for clinical use of FoundationOne®Tracker, a personalized circulating tumor DNA (ctDNA) monitoring assay. In addition, the investigational use only version of the test is now available for use in clinical trials.

FoundationOne Tracker combines genomic information derived from FoundationOne®CDx, Foundation Medicine's tissue-based comprehensive genomic profiling test, with personalized assay design and ctDNA analysis from Natera. The test offers physicians the ability to serially monitor their patients' response to treatment, especially immunotherapies, using a simple blood draw, and to use those insights to make informed decisions for future care. FoundationOne Tracker is now available through an early access program to a limited number of clinical customers, with plans to expand for broad availability in the United States later in 2023.

The current imaging-based standard of care for cancer monitoring is not precise or applicable to all cancer types and treatments, which has an impact on patient outcomes.1-4 For example, immunotherapy is used broadly across patients with advanced cancer, yet there remains an unmet need when assessing response to therapy and disease

progression. FoundationOne Tracker offers physicians a tissue-informed, efficient and precise tool for treatment response monitoring (TRM) to inform personalized treatment strategies. It can be used as a complementary tool to imaging in order to more accurately assess response to treatment and inform next steps in patient care, particularly in cases when imaging is ambiguous or conflicting.

“We developed FoundationOne Tracker to help physicians identify patients who are resistant to their current treatment and may need additional therapy, or those who are responding well to therapy and may benefit from skipping unnecessary doses,” says Foundation Medicine Chief Executive Officer Brian Alexander, M.D., M.P.H. “With this new tool that leverages the molecular fingerprint of the cancer, we hope to maximize the impact of genomic profiling to support a higher degree of personalized cancer care for patients.”

The version of FoundationOne Tracker for research use was **launched in June 2021** for retrospective analysis of archived specimens, providing a cost-effective and efficient path to bring personalized monitoring tools to Foundation Medicine’s biopharma and academic partners. The investigational use version of the test, which may be used for real-time processing of fresh specimens in ongoing prospective studies, is now available to gain earlier insights on treatment response in clinical studies.

“We are pleased to collaborate with Foundation Medicine and support broader access to cutting-edge tools that enable precision medicine,” says Natera’s Chief Executive Officer, Steve Chapman. “This aligns with Natera’s mission to make our personalized monitoring assay technology available to all patients and improve outcomes.”

This launch closely follows two publications demonstrating the clinical validity of FoundationOne Tracker’s value in the TRM and molecular residual disease (MRD) settings, respectively. **Research published in Molecular Oncology** features results from the OMICO-MoST study, the first advanced pan-cancer solid tumor study to demonstrate FoundationOne Tracker’s ctDNA dynamics for treatment response monitoring for two forms of immunotherapy. In another study **recently published in the International Journal of Molecular Sciences**, researchers established the feasibility of ctDNA-based MRD detection in metastatic colorectal cancer patients undergoing surgical resection. These studies are part of the extensive body of evidence both Foundation Medicine and Natera are generating to support the value of integrating tissue-informed ctDNA monitoring in clinical practice.

In February 2022, **FoundationOne Tracker was granted a Breakthrough Device designation** from the FDA for the assay’s use in the detection of MRD in early-stage cancer after curative therapy. The commercial launch of FoundationOne Tracker expands Foundation Medicine’s portfolio of molecular tests, which includes FDA-approved blood- and tissue-based CGP testing options and offers physicians a toolkit of options for detecting genomic alterations and tracking treatment response to help guide personalized cancer care.

FoundationOne Tracker is commercialized by Foundation Medicine.

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About Foundation Medicine: Your Essential Partner in Cancer Care

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on **www.FoundationMedicine.com** and follow us on **Twitter** and **LinkedIn**.

About Natera

Natera™ is a global leader in cell-free DNA testing, dedicated to oncology, women's health, and organ health. Our aim is to make personalized genetic testing and diagnostics part of the standard of care to protect health and enable earlier and more targeted interventions that help lead to longer, healthier lives. Natera's tests are validated by more than 100 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**.

Forward-Looking Statements (Natera)

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 include quotes of management and represent Natera's expectations as of the date of this press release. Natera disclaims any obligation to update these 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, or our expectations of the benefits of our tests and product offerings to patients, providers and payors. 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: Foundation Medicine

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