NEWS RELEASE

Medicare Extends Coverage of Natera's Signatera™ MRD Test to Breast Cancer

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Coverage to include serial monitoring in all subtypes, including hormone receptor-positive, HER2-positive, and triple negative breast cancers

AUSTIN, Texas--(BUSINESS WIRE)-- Natera, Inc. (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced that it has received written confirmation from the Centers for Medicare & Medicaid Services' (CMS) Molecular Diagnostics Services Program (MolDX) that Natera's Signatera molecular residual disease (MRD) test has met coverage requirements for adjuvant and recurrence monitoring in patients with stage IIb or higher breast cancer. The coverage applies across all subtypes of the disease, including hormone receptor (HR)-positive, HER2-positive, and triple negative breast cancers. This decision adds to Medicare's prior coverage of Signatera in colorectal cancer, muscle-invasive bladder cancer, and pan-cancer immunotherapy monitoring.

"Signatera is a critical innovation that can help us to enhance care management for patients with breast cancer," said Jenny C. Chang, M.D., treating oncologist and director of the Houston Methodist Dr. Mary and Ron Neal Cancer Center. "The five-year recurrence rates for breast cancer are estimated to be as high as 30 percent,and traditional methods for detecting recurrence can be inaccurate. Signatera addresses a critical unmet need and improves our ability to accurately predict recurrence risk from breast cancer."

The decision by CMS was primarily based on evidence from the Exploratory Breast Lead Interval Study (EBLIS), published in Clinical Cancer Research.1 In the study, patients with breast cancer across all subtypes were monitored with Signatera every 6 months after surgery, resulting in early relapse detection with 89% sensitivity, 100% specificity, and a diagnostic lead time of up to 2 years (median 8.9 months) ahead of radiographic imaging.

Signatera MRD status was also found to be the most significant risk factor for recurrence across all subtypes of disease. This study is one of several that support the use of Signatera in breast cancer, and one of over 40 peer-reviewed publications across solid tumors.

In addition to detecting recurrence and helping to inform patient management decisions, Signatera can offer peace of mind to those patients who test serially negative. According to Chloe Crampton, a Signatera patient living with breast cancer, “Signatera has given me and my care team more information about my disease, but most importantly, it has allowed me to live a life with less anxiety and more hope.”

Breast cancer is the most common cancer in women in the United States, with an estimated 2022 incidence and mortality of 287,850 and 43,250, respectively. There are more than 3.8 million women with a history of breast cancer in the U.S.2 The median age of diagnosis is approximately 60 years, and over 40% of patients are diagnosed at age 65 years or older.3

“Extending Medicare coverage for Signatera to patients with breast cancer, irrespective of subtype, is a real milestone for precision oncology and a game changer for patients,” said Minetta Liu, M.D., chief medical officer of oncology at Natera. “Our tumor-informed assay enables oncologists to more confidently identify patients at high risk of recurrence, informing decisions related to active surveillance via imaging, as well as decisions to escalate or de-escalate treatment.”

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 three 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 identify recurrence earlier and to help optimize treatment decisions.

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 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

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, or coverage and reimbursement determinations from third-party 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**.

Contacts

References

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2. Breast Cancer Facts and Statistics. Breastcancer.org. **https://www.breastcancer.org/facts-statistics**. Last updated on January 18, 2023.
3. Tesarova P. Specific Aspects of Breast Cancer Therapy of Elderly Women. Biomed Res Int. 2016;2016:1381695.

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