NEWS RELEASE

Signatera™ CDx Approved by the FDA as a Companion Diagnostic in Muscle-Invasive Bladder Cancer (MIBC)

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Marks the first FDA-approved use of personalized molecular residual disease (MRD) testing to guide treatment decisions

Solidifies Natera's Treatment on MRD (TOMR) approach as the new standard of care in MIBC, enabling precision interventions for MRD-positive patients while sparing MRD-negative patients from potentially unnecessary treatment

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced that the U.S. Food and Drug Administration (FDA) has approved Signatera CDx as a companion diagnostic (CDx) for use with adjuvant atezolizumab (Tecentriq®) immunotherapy in MIBC.

This is the first companion diagnostic approval in the field of blood-based MRD. It is a significant milestone in the industry-wide shift toward personalized, MRD-guided cancer care, in which treatment decisions may depend on Signatera™ MRD status, and interventions may be delayed or deferred for patients who remain MRD-negative. Supported by more than 185 peer-reviewed publications and Medicare coverage across multiple cancer types (including Bladder, Breast, Lung, Colorectal, Ovarian, and pan-cancer immunotherapy monitoring), Signatera has become a cornerstone of precision oncology.

Signatera CDx has been approved by the FDA for use with adjuvant atezolizumab (Tecentriq®) to identify patients with MIBC who are ctDNA MRD-positive and may benefit from treatment. This follows **The New England Journal of**

Medicine publication in October 2025 of the landmark, global Phase III IMvigor011 trial, sponsored by Genentech. The trial results demonstrated that Signatera MRD-positive patients treated with immunotherapy achieved significant improvements in disease-free survival (DFS) and overall survival (OS), while Signatera MRD-negative patients achieved 97% 2-year OS with no adjuvant therapy at all.

“The practice-changing IMvigor011 trial and this approval signal a transformation in cancer care, where MRD is guiding when to treat, whom to treat, and how to treat more precisely,” said Professor Thomas Powles, lead principal investigator of IMvigor011 and Chair of Barts Cancer Centre at St. Bartholomew’s Hospital. “Historically, we relied on imaging to tell us when cancer had returned, but that also meant millions of cancer cells were already present in the body. As we saw with IMvigor011 and in several other trials, Signatera detected tumor DNA at an earlier timepoint and provided us with a significant head start to improve outcomes for patients.”

“For bladder cancer patients and families, the period after bladder removal can be filled with uncertainty,” said Meri-Margaret Deoudes, CEO of the Bladder Cancer Advocacy Network. “Approaches like Signatera can help clarify which patients are more likely to experience recurrence, giving clinicians additional important information as they consider next steps. Our priority is ensuring that patients and families have access to tools that support informed decision-making, reduce unnecessary treatment when possible, and help guide timely care when it’s needed.”

“This FDA approval is a major milestone for the field of precision oncology and personalized medicine,” said Solomon Moshkevich, president of clinical diagnostics at Natera. “This validates the vision that Natera introduced 10 years ago and solidifies Signatera MRD as the new standard of care in muscle-invasive bladder cancer. With our growing portfolio of TOMR trials and our recent innovations in ultrasensitive genome-based MRD and phased variant technologies, Natera continues to drive forward the science across all cancer types.”

There are approximately 30,000 new diagnoses of MIBC each year in the U.S. and 150,000 globally.1-5 Radical cystectomy, with or without neoadjuvant therapy, is associated with long-term disease control in approximately half of patients with muscle-invasive bladder cancer, but it has historically been difficult to identify which patients are likely to recur and to offer them effective, personalized therapy while sparing others from unnecessary treatment.5-6 With IMvigor011, there is now prospective evidence showing that MRD can guide care for patients in this setting and adds to the growing body of evidence on Signatera across the bladder cancer continuum.

Notes

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

References

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5. Stein JP, Lieskovsky G, Cote R, et al. Radical cystectomy in the treatment of invasive bladder cancer: long-term results in 1,054 patients. J Clin Oncol. 2001;19(3):666–675. doi:10.1200/JCO.2001.19.3.666
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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 350 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 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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