NEWS RELEASE

Signatera™ Receives Regulatory Approval in Japan as a Companion Diagnostic in Muscle-Invasive Bladder Cancer

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Second PMDA approval for Signatera in three months and first PMDA-approved CDx in MRD-guided care; commercial launch expected in 1H'27, pending final reimbursement and pricing

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced that its Signatera test has received regulatory approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA) as a companion diagnostic (CDx) in muscle-invasive bladder cancer (MIBC).

This approval supports the use of the Signatera test to guide adjuvant atezolizumab (Tecentriq®) treatment decisions in patients with MIBC. Natera expects to commercially launch Signatera for MIBC in Japan in the first half of 2027, following the PMDA's approval of atezolizumab in MIBC.

Regulatory approval was supported by data from IMvigor011, a randomized, double-blind phase III clinical trial that evaluated Signatera-guided adjuvant atezolizumab in patients with MIBC. The trial included more than 20 participating sites in Japan, giving Japanese clinicians firsthand experience with Signatera-guided treatment in this setting.

This marks Signatera's second PMDA authorization in Japan, after receiving approval in colorectal cancer in June 2026. It follows the U.S. Food and Drug Administration's (FDA) approval of Signatera as a CDx for adjuvant atezolizumab in MIBC (and the approval by the FDA of atezolizumab), as well as the recently published Category 1 recommendation for MRD-guided adjuvant atezolizumab in the National Comprehensive Cancer Network®

(NCCN®) Clinical Practice Guidelines for Bladder Cancer.

Bladder cancer affects more than 34,000 people in Japan each year,1 with approximately 20–25% of newly diagnosed cases classified as muscle-invasive.2 MIBC carries a higher risk of recurrence and greater treatment complexity than earlier-stage disease, underscoring the need for precision tools that can help clinicians individualize treatment decisions in the adjuvant setting.

“We look forward to launching this second Signatera MRD indication in Japan, giving patients with muscle-invasive bladder cancer a proven diagnostic tool to guide treatment decisions in the first year after surgery,” said Alexey Aleshin, M.D., corporate chief medical officer and general manager of oncology, Natera. “We value our growing partnership with the Japanese oncology community, which has been a leader in adopting MRD into clinical trials and into clinical practice.”

References

1. World Cancer Research Fund International. Bladder cancer statistics. Accessed June 26, 2026. **https://www.wcrf.org/preventing-cancer/cancer-statistics/bladder-cancer-statistics/**
2. Gakis G. Management of Muscle-invasive Bladder Cancer in the 2020s: Challenges and Perspectives. Eur. Urol. Focus. 2020;6(4):632–638.

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**.

Notes

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

Investor Relations: Mike Brophy, CFO, Natera, Inc., **investor@natera.com**
Media: Lesley Bogdanow, VP of Corporate Communications, Natera, Inc., **pr@natera.com**

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