NEWS RELEASE

Natera Submits Signatera™ to Japan's PMDA for Approval as a Companion Diagnostic in Muscle-Invasive Bladder Cancer

2026-08-05

Follows Signatera's recent U.S. FDA approval in MIBC and Japanese PMDA approval in CRC

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

The submission advances Natera's growing presence in Japan, where Signatera received PMDA approval in colorectal cancer in June, becoming the country's first PMDA-approved molecular residual disease (MRD) test.

The MIBC application is supported by data from IMvigor011, a randomized, double-blind Phase 3 clinical trial. It also builds on recent milestones for Signatera in MIBC: the U.S. FDA's approval of Signatera™ CDx as a companion diagnostic for adjuvant atezolizumab (Tecentriq®); and a Category 1 recommendation for Signatera 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 Globally, approximately 20–25% of newly diagnosed bladder cancers are muscle-invasive.2 MIBC is a more aggressive form of the disease, associated with higher recurrence risk and treatment complexity.

“Signatera is a proven tool in bladder cancer management, and this submission reflects our commitment to bringing precision diagnostics to patients in Japan,” said Alexey Aleshin, M.D., corporate chief medical officer and general manager of oncology at Natera. “We look forward to engaging with the PMDA and to improving outcomes for patients around the world.”

Notes

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

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**.

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

Source: Natera, Inc.