



NEWS RELEASE

Natera Submits Signatera™ CDx PMA to FDA

2026-02-02

Application backed by landmark phase 3 data validating MRD-guided treatment in bladder cancer

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced the submission of its premarket approval (PMA) to the U.S. Food and Drug Administration (FDA) for Signatera™ CDx for detection of molecular residual disease (MRD) in patients with muscle-invasive bladder cancer (MIBC) who may benefit from treatment with atezolizumab (Tecentriq®).

This submission is supported by data from the randomized, double-blind, phase 3 IMvigor011 clinical trial, which met its primary endpoint and demonstrated the benefits of Signatera-guided therapy in MIBC. In the study, Signatera-positive patients treated with atezolizumab (Tecentriq®) had statistically significant and clinically meaningful improvements in disease-free survival and overall survival, compared with placebo. The trial also showed that Signatera-negative patients had a low risk of recurrence without adjuvant immunotherapy. Results were featured in a Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress on October 20, 2025, with a concurrent publication in *The New England Journal of Medicine*.

Bladder cancer is the sixth most common cancer in the United States¹ and MIBC represents 20-25% of the newly diagnosed cases.² Radical cystectomy (with or without neoadjuvant therapy) is curative for approximately half of these patients, but until now it has been very challenging to identify which patients are likely to recur and to offer them effective, personalized therapy while sparing the others from unnecessary treatment.^{3,4} The IMvigor011 trial, sponsored by Genentech, a member of the Roche Group, was designed to address that challenge.

“Submitting this PMA represents an important step toward making MRD-guided treatment a reality for patients with muscle-invasive bladder cancer,” said Alexey Aleshin, M.D., general manager of oncology and corporate chief



medical officer at Natera. “If approved, we believe Signatera CDx has the potential to be the first companion diagnostic MRD test that helps guide treatment decisions and improve outcomes for patients.”

References

1. National Comprehensive Cancer Network, Bladder Cancer. NCCN Clinical practice guidelines in oncology (NCCN Guidelines). Version 4.2021.
2. Gakis G. Management of Muscle-invasive Bladder Cancer in the 2020s: Challenges and Perspectives. *Eur. Urol. Focus.* 2020;6(4):632-638.
3. 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
4. Yafi FA, Aprikian AG, Chin JL, et al. Contemporary outcomes of 2,287 patients with bladder cancer treated with radical cystectomy: a Canadian multicentre experience. *BJU Int.* 2011;108(4):539–545. doi:10.1111/j.1464-410X.2010.09912.x

Notes

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

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 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.