



NEWS RELEASE

# Natera Announces Positive Surveillance Analysis from the Randomized Phase III IMvigor011 Trial in Muscle-Invasive Bladder Cancer

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Data demonstrates that MIBC patients who remain Signatera MRD-negative after surgery may be spared from adjuvant treatment, with 100% overall survival at 12 months

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced an analysis from the IMvigor011 study that was presented at the European Association of Urology (EAU) Congress 2024 in Paris, France. The analysis evaluates outcomes in muscle-invasive bladder cancer (MIBC) patients who tested serially negative with Signatera™, Natera's personalized and tumor-informed molecular residual disease (MRD) test.

Sponsored by Genentech, a member of the Roche group, IMvigor011 is a global, double-blind, randomized, Phase III trial, in which high-risk MIBC patients are serially tested with Signatera for up to 12 months post cystectomy. Patients who test Signatera MRD-positive at any point during the 12-month surveillance window are randomized to the anti-PDL1 atezolizumab (Tecentriq®) vs. placebo. Patients who remain Signatera-negative at completion of the testing window are not randomized but continue to undergo radiographic imaging thereafter.

The analysis presented at the EAU Congress evaluated clinical outcomes in 171 high-risk MIBC patients who entered screening for IMvigor011 and remained MRD-negative during the surveillance window. Key takeaways from the presentation include:

- Overall survival (OS) rates of 100% at 12 months and 98% at 18 months, in patients who remained serially



MRD-negative.

- Disease-free survival (DFS) rates of 92% at 12 months and 88% at 18 months, in patients who remained serially MRD-negative.
- Concludes that patients who remain MRD-negative on serial testing may be spared from adjuvant treatment.

“IMvigor011 is an important randomized study that is designed to address a critical unmet need for the more than 35,000 patients a year diagnosed with muscle-invasive bladder cancer,” said John Simmons, vice president, BioPharma at Natera. “We believe the results of this trial will further demonstrate how Signatera can help personalize treatment decisions and improve outcomes for bladder cancer patients. Together with Professor Powles and our collaborators at Genentech, we look forward to the full trial read-out which could serve as the basis of Natera’s first FDA companion diagnostic submission for Signatera.”

This presentation follows a study published in **Nature** based on the phase III randomized IMvigor010 trial, which showed that patients who tested Signatera MRD-positive after radical cystectomy received significant benefit from adjuvant immunotherapy with atezolizumab, while Signatera-negative patients derived no significant benefit from adjuvant therapy.

**As previously announced** in October 2023, Natera submitted the first module of its premarket approval application to the U.S. Food and Drug Administration (FDA) for Signatera as a companion diagnostic (CDx) assay for patients with MIBC.

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

## About Signatera

**Signatera** is a personalized, tumor-informed, molecular residual disease test for patients previously diagnosed with cancer. Custom-built for each individual, Signatera uses circulating tumor DNA to detect and quantify cancer left in the body, identify recurrence earlier than standard of care tools, and help optimize treatment decisions. The test is available for clinical and research use and is covered by Medicare for patients with colorectal cancer, breast cancer, ovarian cancer and muscle-invasive bladder cancer, as well as for immunotherapy monitoring of any solid tumor. Signatera has been clinically validated across multiple cancer types and indications, with published evidence in more than 50 peer-reviewed papers.

## 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 180 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](http://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](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

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