



NEWS RELEASE

IMvigor011 Bladder Cancer Trial Achieves Positive Results, with Signatera™ Strongly Predicting Adjuvant Immunotherapy Benefit

2025-08-18

Topline results from the trial show that Signatera-positive patients treated with atezolizumab (Tecentriq®) had statistically significant and clinically meaningful improvements in disease-free survival and overall survival

IMvigor011 is the first prospective phase III study in muscle-invasive bladder cancer to read out that uses a personalized, ctDNA MRD*-guided approach

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced positive topline results from the randomized, phase III IMvigor011 clinical trial in muscle-invasive bladder cancer (MIBC). The trial is sponsored by Genentech, a member of the Roche Group.

IMvigor011 utilizes the Signatera ctDNA test in patients with MIBC to detect molecular residual disease (MRD) in the bloodstream after surgery and predict who will benefit from adjuvant treatment with the cancer immunotherapy atezolizumab (Tecentriq®). Approximately 760 patients were enrolled in the surveillance phase of the trial and underwent serial Signatera testing for up to 12 months post surgery. Patients were randomized to treatment with atezolizumab or placebo if they tested Signatera-positive and remained free of cancer recurrence on imaging with treatment administered every 4 weeks for 12 cycles or up to one year. Patients who consistently tested Signatera-negative were not randomized to treatment but continued to be followed up with radiographic imaging and ctDNA MRD testing.

Topline results from IMvigor011 demonstrated a statistically significant and clinically meaningful improvement in



disease-free survival and overall survival for Signatera-positive patients treated with atezolizumab. Natera expects trial data to be presented at an upcoming medical conference.

“The results of IMvigor011 are very significant, opening the door for a new treatment paradigm for bladder cancer patients who are positive for recurrence on a molecular level but have no evidence of disease on imaging,” said Professor Thomas Powles, MBBS, MRCP, M.D., lead principal investigator of the study; Barts Cancer Institute QMUL. “We look forward to presenting the positive results later this year.”

“Importantly, IMvigor011 could change how resectable bladder cancer is managed for the tens of thousands of patients diagnosed with MIBC each year,” said Alexey Aleshin, M.D., general manager of oncology and corporate chief medical officer at Natera.

Natera will finalize its premarket approval application to the U.S. Food and Drug Administration for Signatera as a companion diagnostic for the selection of patients with MIBC to be treated with atezolizumab after cystectomy.

In addition to the topline result released today, **a preliminary analysis** of Signatera-negative patients from IMvigor011 was presented at the European Association of Urology in April 2024. The data highlighted that post-operative patients who remain Signatera-negative on serial testing had excellent outcomes without adjuvant treatment. The analysis showed that 171 patients who remained Signatera-negative during the surveillance window had overall survival rates of 100% at 12 months and 98% at 18 months, and disease-free survival rates of 92% at 12 months and 88% at 18 months after surgery.

Notes

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

*ctDNA MRD = circulating tumor DNA molecular residual disease

About Natera

Natera™ is a global leader in cell-free DNA and genetic 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 supported by more than 300 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. 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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Source: Natera, Inc.