NEWS RELEASE

Signatera™ Receives Regulatory Approval in Japan for Colorectal Cancer

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First PMDA-approved molecular residual disease (MRD) test in Japan, supporting the use of Signatera in the adjuvant setting

Commercial launch expected by year-end, 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 Signatera has received regulatory approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

This approval supports the use of Signatera for patients with colorectal cancer (CRC) in the adjuvant setting and makes Signatera the first PMDA-approved MRD test in Japan. Natera expects to commercially launch Signatera for CRC in Japan by the end of 2026, subject to final pricing determination.

More than 150,000 people are diagnosed with CRC in Japan each year,1 making it one of the country's most common cancers. This disease burden is comparable to that of the United States and highlights the need for more individualized tools to help Japanese clinicians inform adjuvant treatment decisions. Approval of Signatera fulfills this unmet need.

Commercialization of Signatera will be supported by an existing position statement from the Japan Society of Clinical Oncology (JSCO) and guidance from the Japanese Society of Medical Oncology (JSMO), which recommends the use of MRD testing in CRC.

“This approval marks an important milestone for Japanese patients with colorectal cancer,” said Takayuki Yoshino, M.D., executive advisor to hospital director and director, department of global oncology, National Cancer Center Hospital East, chairman of JSCO, president of JSMO, and program director of the CIRCULATE-Japan Project. “Clinicians and medical societies in Japan deeply value the strength of the clinical evidence on Signatera, demonstrating its ability to inform treatment decisions.”

Regulatory approval was supported by positive evidence from the GALAXY clinical trial, which demonstrated that patients who test MRD-positive after surgery derive significant benefit from adjuvant chemotherapy, while those who test MRD-negative derive no benefit from adjuvant chemotherapy. With analysis of 2,240 samples, this is one of the largest and most comprehensive prospective studies of MRD testing in resectable CRC and is part of the CIRCULATE-Japan platform involving thousands of CRC patients and >150 Japanese institutions.

“We are grateful to the investigators and patients who helped build the clinical evidence supporting this milestone,” said Alexey Aleshin, M.D., corporate chief medical officer and general manager of oncology at Natera. “As we prepare for commercial launch in CRC, we remain committed to expanding global access to Signatera across additional cancer types, with muscle-invasive bladder cancer representing our next planned submission in Japan.”

References

1. National Cancer Center Japan, Cancer Information Service, colorectal cancer statistics, 2023 incidence data.

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**

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