



NEWS RELEASE

New MultiCenter Prospective Study Demonstrates Signatera's Clinical Utility in Merkel Cell Carcinoma

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Study reports high accuracy of Signatera for surveillance of MCC patients, suggests potential to reduce frequency of surveillance imaging

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced a new study published in the *Journal of Clinical Oncology* highlighting the utility of its personalized and tumor-informed molecular residual disease (MRD) test, Signatera, for surveillance in Merkel cell carcinoma (MCC). The full study can be found [here](#).

MCC is an aggressive skin cancer with high mortality and a recurrence rate of 40% within 5 years.¹ MRD testing using a viral antibody is recommended by the National Comprehensive Cancer Network (NCCN)², but this tumor marker is only present in 52% of patients and has several known limitations³⁻⁴. There is an unmet need for improved MRD testing technologies that are applicable to all patients, regardless of their viral status.

This prospective, multicenter, observational study included 319 patients with stage I-IV MCC. Signatera was used to assess ctDNA levels at the time of enrollment, and every 3 months during the surveillance period. Key findings include:

- Signatera showed a test sensitivity of approximately 95% for detecting clinically evident disease at time of enrollment.
- ctDNA positivity during surveillance was associated with up to 20 times higher risk of recurrence than persistently ctDNA-negative patients.
- At 12 months of surveillance, the recurrence-free probability was 9% among patients with a positive ctDNA

result at any time, compared with 91% for patients who remained ctDNA-negative.

“There is a strong need for highly accurate biomarkers in merkel cell carcinoma, an incredibly aggressive and rare form of skin cancer,” said Lisa Zaba, M.D., Ph.D., associate professor of dermatology, director of the MCC multi-disciplinary clinic and member of the supportive oncodermatology group at the Stanford Cancer Center. “Our study shows that a tumor-informed MRD test can inform prognosis and guide surveillance in patients with MCC, regardless of tumor viral status.”

“We are encouraged by the excellent performance of Signatera in this study, where high prognostic accuracy was demonstrated, and where we can see the significant clinical utility of MRD testing for detecting recurrence in MCC patients,” said Angel Rodriguez, M.D., senior medical director at Natera and co-author of the study. “We are optimistic that Signatera will become a standard monitoring tool in this highly lethal cancer type, enabling clinicians to select patients with MRD who might benefit most from adjuvant therapy and better determine who may or may not need more frequent imaging with a high degree of confidence.”

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 70 peer-reviewed papers.

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 validated by more than 200 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.

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.

References

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2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Merkel Cell Carcinoma Version 1.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 25, 2024.
3. Paulson KG, Lewis CW, Redman MW, et al. Viral oncoprotein antibodies as a marker for recurrence of Merkel cell carcinoma: A prospective validation study. *Cancer*. 2017;123(8):1464-1474.
4. Paulson KG, Carter JJ, Johnson LG, et al. Antibodies to merkel cell polyomavirus T antigen oncoproteins reflect tumor burden in merkel cell carcinoma patients. *Cancer Res*. 2010;70(21):8388-97.

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