NEWS RELEASE

# New Publication Establishes Strong Clinical Validation of Signatera™ for MRD Assessment in Lymphoma

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Signatera demonstrates 100% positive predictive value for treatment response assessment, detects recurrence months earlier than imaging, and supports precise, individualized lymphoma management through serial ctDNA monitoring

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced the **publication** of new data in Blood Neoplasia, validating the prognostic and predictive value of Signatera in patients with both newly diagnosed and relapsed/refractory (R/R) lymphoma.

PET/CT scans serve as the standard tool for assessing treatment response in lymphoma, but their performance is limited, with positive predictive value (PPV) reported as low as 50% and negative predictive value (NPV) as low as 80%.1-3 To address this unmet need, the National Comprehensive Cancer Network® (NCCN®) guidelines were recently updated to include circulating tumor DNA (ctDNA)-based molecular residual disease (MRD) assessment as a confirmatory method for positive PET/CT scans.

The prospective, real-world study conducted by Galanina et al. evaluated a representative cohort of 144 newly diagnosed or R/R patients across 14 distinct indolent and aggressive lymphoma subtypes, with analysis of 1,105 plasma samples collected at baseline, during therapy, at the end of therapy (EOT), and throughout surveillance. Signatera status was compared to standard-of-care imaging and clinical outcomes to evaluate its predictive and prognostic utility in real-world disease management. Key findings include:

- Superior prognostic ability over PET/CT:
    - EOT Signatera-positivity was prognostic of significantly inferior event-free survival (EFS) (adj HR: 45.33;

p<0.0001) and was the strongest independent predictor of EFS in a multivariate analysis (HR: 80.83 vs. PET/CT HR: 5.18; p<0.001).
    - Signatera demonstrated superior PPV vs. PET/CT at EOT (100% vs. 62%; p<0.0001). Among discordant ctDNA/PET cases, the Signatera test result was confirmed as correct in 85% of instances.
    - During surveillance, Signatera-positivity was strongly prognostic (HR: 33.74; p<0.0001), demonstrating a sensitivity of 91% and specificity of 92%.
- Predictive of response across the treatment continuum:
    - Signatera clearance during 1L therapy was associated with significantly improved EFS (adj HR: 8.57; p=0.0005).
    - For R/R patients post CAR-T therapy, Signatera clearance was associated with durable remission, while Signatera-positive patients experienced disease progression or death, and a median durable treatment interval of 16.1 vs. 1.97 months, respectively (p=0.0091).

"Lymphoma is an incredibly diverse group of cancers and this study shows that Signatera delivers consistent and reliable insights across multiple lymphoma subtypes," said Natalie Galanina, M.D., corresponding author of the study. "Findings suggest that Signatera can complement traditional imaging by identifying patients who may benefit from earlier changes in management. ctDNA/MRD assessment is transforming how we evaluate treatment response, offering the opportunity to move beyond conventional imaging and toward more precise, individualized, and dynamic treatment decisions. I'm excited to incorporate this approach into routine clinical practice to further personalize care for patients with hematologic malignancies."

"The ability to reliably detect and monitor molecular residual disease over time has the potential to impact the approach to treatment of lymphoma," said Minetta Liu, M.D., chief medical officer, oncology and early cancer detection, Natera. "By enabling visibility into recurrence earlier than imaging, Signatera testing creates a window for more timely, risk-adapted interventions that could meaningfully change patient management."

## References


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3. Adams HJA, Nievelstein RAJ, Kwee TC. Prognostic value of complete remission status at end-of-treatment FDG-PET in R-CHOP-treated diffuse large B-cell lymphoma: systematic review and meta-analysis. British Journal of Haematology. 2015;170(2):185-191. doi:10.1111/bjh.13420.


## 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 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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