



NEWS RELEASE

Natera's Landmark RenaCARE Study Demonstrates Significant Diagnostic and Clinical Utility of Renasight™ in Chronic Kidney Disease

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Study found 1 in 5 patients was positive for a genetic cause of CKD, 1 in 2 positive patients received a new or reclassified diagnosis, and 1 in 3 positive patients had a change in treatment plan

Diagnostic yield and utility exceed clinical precedents for implementation of routine genetic testing within an at-risk population¹⁻⁶

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, announced that the Journal of the American Society of Nephrology recently published **initial results** from RenaCARE (Renasight Clinical Application, Review, and Evaluation), a multisite, real-world, prospective study assessing the frequency and impact of genetic testing within the chronic kidney disease (CKD) population. The study enrolled 1,623 patients with CKD across 31 community and academic medical centers. Patients were tested with Renasight, Natera's 385-gene kidney genetic test.

As the fastest-growing non-communicable disease in the U.S., CKD affects more than 37 million people (approximately 1 in 7 adults).⁷ It adds a significant economic burden to the healthcare system, with 23.5% of Medicare spending, \$85.4 billion, related to the management and treatment of CKD in 2020.⁸

CKD has a vast spectrum of underlying causes and the current standard of care relies on basic measurements of kidney function, imaging, and histology to inform diagnosis.⁹ This limited approach has left significant gaps in the accuracy, completeness, and specificity of patient diagnoses. Genetic testing can address many of these limitations



by identifying the underlying origin of disease, enabling physicians to properly diagnose and stratify CKD patients.

RenaCARE key findings

In the RenaCARE study, 20.8% of CKD patients had a positive genetic finding. Of those, 48.8% of patients received a new or reclassified diagnosis and 34% received information on disease subtype. The results also showed that 90.7% of positive patients had a change in management, including 32.9% with a change in treatment plan.

The RenaCARE findings highlight how genetic testing can address critical limitations in the current approach to diagnosing CKD, across categories:

- Non-specific CKD diagnosis: 46.0% of enrolled patients had CKD attributed to clinical categories based on non-specific criteria, including diabetes, hypertension, hematuria, and proteinuric disease suggestive of a primary glomerulopathy. In many cases, these conditions are found to be comorbidities and not the main cause of disease. Failing to further investigate the primary cause can hinder appropriate treatment. Within these categories, 14.7% received a positive genetic result – of which 70.0% had a new or reclassified diagnosis, and 22.5% had a change in treatment plan.
- Undefined subtype for an existing clinical diagnosis: 16.1% of enrolled patients were diagnosed with cystic nephropathy, where defining a subtype can significantly impact disease prognosis and treatment plan. Within this category, 49.6% received a positive genetic result – of which 79.2% received a genetic subtype confirming the clinical presentation, and 49.2% had a change in treatment plan.
- Unknown cause of CKD: 8.1% of patients were characterized with CKD of unknown cause, limiting the ability to use specific treatment options. For those who screen positive, genetic testing can identify a more targeted treatment plan. Within this category, 18.2% received a positive genetic result – of which 87.5% received a new diagnosis, and 23.8% had a change in treatment plan.
- Treatment with targeted therapies: Diagnoses based solely on clinical symptoms without detailed genetic information limit opportunities to prescribe currently available, targeted therapeutics or enroll patients in clinical trials. In the study, 35.5% of patients with positive results received a diagnosis that could make them eligible for available therapeutics.
- Use of unnecessary and invasive diagnostic biopsies: In many cases, genetic testing can clarify a diagnosis and may obviate the need for invasive procedures that carry complication risks and often still require subsequent clarification. In the study, 19.4% of patients who tested positive with Renasight had a biopsy prior to genetic testing. Of those, 71.1% received a new diagnosis based on their Renasight result, suggesting that Renasight can provide important information to potentially avoid diagnostic biopsies in the future.

“RenaCARE demonstrates the value of genetic testing to improve the precision of clinical diagnoses for patients with CKD, enabling clinicians to tailor management strategies and therapies,” said Ali Gharavi, M.D., professor of medicine and chief of the Division of Nephrology at New York-Presbyterian/Columbia University Irving Medical Center, and principal investigator of the RenaCARE study. “Our study supports the broader integration of genetic testing into kidney care to initiate or alter management as early as possible.”

Additional details on unmet needs within CKD and how genetic testing can address gaps in care can be found in a white paper published today, entitled, “**Insights from RenaCARE: Genetics Driving Precision Medicine in Kidney Disease.**”

About the Renasight test

The Renasight™ test is a germline genetic test that screens for hereditary causes of kidney disease. It is indicated for patients with diagnosed kidney disease and is run from a patient’s blood or saliva sample. Providers can use the Renasight test to identify a genetic predisposition, clarify a clinical diagnosis, or identify the etiology of an unknown kidney disease to help inform medical management. Additionally, genetic counseling and familial testing can be offered based on the test result. The test has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

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 150 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, or our expectations 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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