CATE Clinical Trial Launched to Demonstrate the Clinical Utility of ctDNA-Guided Treatment in Breast Cancer Using the Ultrasensitive NeXT Personal Test

September 10, 2025

FREMONT, Calif.--(BUSINESS WIRE)--Sep. 10, 2025-- Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for precision oncology, today announced its collaboration with a leading breast cancer team from Yale Cancer Center for a clinical trial titled “A single arm phase II trial of circulating tumor DNA-guided adjuvant therapy with elacestrant in hormone receptor positive HER2 negative breast cancers at risk for late recurrence (CATE),” a novel ctDNA-guided study aimed at improving outcomes in patients with breast cancer.

The prospective, multi-center trial, sponsored by the Translational Breast Cancer Research Consortium (TBCRC) and led by Dr. Mariya Rozenblit and Dr. Maryam Lustberg at Yale Cancer Center, will investigate whether earlier, ultra-sensitive ctDNA-guided intervention can prevent metastatic relapse and improve outcomes for patients with HR+/HER2- breast cancer.

HR+/HER2- breast cancer, which accounts for over 70% of all cases, poses a significant challenge due to the risk of late recurrence. The CATE trial utilizes the ultrasensitive Personalis NeXT Personal® test to identify the earliest molecular signs of recurrence, ahead of standard imaging. Patients who test positive will be preemptively treated with elacestrant, a next-generation therapy, with the goal of eliminating cancer before it becomes metastatic.

“CATE is addressing the critical unmet need for better surveillance in patients who are at risk of late recurrence and the potential for a ctDNA-guided approach to establish a new proactive treatment option,” said Mariya Rozenblit, MD, Assistant Professor of Medicine (Medical Oncology and Hematology) at Yale Cancer Center.

“The future of oncology care depends on not just identifying recurrence earlier, but on acting earlier to improve a patient’s course. This collaboration with Yale's leading oncologists is another step in our mission to transform cancer management,” said Dr. Richard Chen, Chief Medical Officer and EVP of R&D at Personalis. “The CATE study is designed to generate the clinical utility data needed to introduce ctDNA-guided therapy into clinical practice for HR+ breast cancer patients, with the goal of empowering oncologists to intervene earlier and improve patient outcomes.”

About Personalis, Inc.

At Personalis, we are transforming the active management of cancer through breakthrough personalized testing. We aim to drive a new paradigm for cancer management, guiding care throughout the patient journey. Our highly sensitive assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect minimal residual disease (MRD) and recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development. Personalis is based in Fremont, California. To learn more, visit www.personalis.com and connect with us on LinkedIn and X (Twitter).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this press release that are not historical are “forward-looking statements” within the meaning of U.S. securities laws, including statements relating to the attributes, advantages, sensitivity, specificity, clinical validity or clinical utility of the NeXT Personal test or to the potential impact or expected benefits of the CATE study. Such forward-looking statements involve known and unknown risks and uncertainties and other factors that may cause actual results to differ materially from any anticipated results or expectations expressed or implied by such statements, including the risks, uncertainties and other factors that relate to the ability of NeXT Personal to detect small traces of ctDNA, detect residual or recurrent cancer early, or impact cancer care or management (including for escalation or de-escalation of treatment). These and other potential risks and uncertainties that could cause actual results to differ materially from the results predicted in these forward-looking statements are described under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Personalis’ Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed with the Securities and Exchange Commission on August 5, 2025. All information provided in this release is as of the date of this press release, and any forward-looking statements contained herein are based on assumptions that we believe to be reasonable as of this date. Personalis undertakes no duty to update this information unless required by law.

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