New Data Shows NeXT Personal® Identifies Breast Cancer Patients Receiving Neoadjuvant Therapy that are at High Risk for Relapse

June 2, 2025

FREMONT, Calif.--(BUSINESS WIRE)--Jun. 2, 2025-- Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for precision oncology, announced the presentation of new clinical results from the PREDICT DNA and SCANDARE studies highlighting the capabilities of its ultrasensitive NeXT Personal circulating tumor DNA (ctDNA) blood test for monitoring and predicting neoadjuvant therapy (NAT) response in triple negative breast cancer (TNBC), one of the most aggressive types of breast cancer.

“Many triple negative breast cancer patients receive neoadjuvant therapy prior to surgery as standard of care. The data from these two studies independently suggest that an ultrasensitive ctDNA assay like NeXT Personal could help these patients better understand their risk of relapse, with the potential to help inform the need for additional therapy,” said Richard Chen, MD, Chief Medical Officer and Executive Vice President, R&D at Personalis. “We believe this data, once published, can form the basis for seeking reimbursement coverage for neoadjuvant therapy monitoring in breast cancer. We are excited to continue to work with leading collaborators to expand the data around the use of NeXT Personal in breast cancer with the goal of helping breast cancer patients optimize their care.”

Results from the PREDICT DNA study were presented yesterday by Dr. Natasha Hunter, MD, University of Washington, at the American Society for Clinical Oncology (ASCO) 2025 Annual Meeting in Chicago in an oral presentation titled “Circulating tumor DNA, pathologic response after neoadjuvant therapy, and survival: First results from TBCRC 040 (the PREDICT DNA trial).”

“The PREDICT DNA study prospectively evaluated ctDNA in early-stage patients with HER2-positive and triple negative breast cancer. The trial was initiated a decade ago and accrued 228 patients across 22 sites in the United States, and was statistically designed and powered for analysis of ctDNA to predict for pathologic complete response (pCR), and whether ctDNA could be a prognostic test to identify patients at high vs. very low risk for recurrence,” said Dr. Ben Park, MD PhD, Vanderbilt-Ingram Cancer Center. “We partnered with Personalis because of their technology's ultrasensitive detection of ctDNA down to 1 to 3 parts per million. Our results demonstrate that patients who 'clear' their ctDNA after upfront chemotherapy have excellent outcomes that mirror those with pCR, identifying a group of patients who, despite having residual disease at the time of surgery, will be at extremely low risk for recurrence. Conversely, those with detectable ctDNA after upfront chemotherapy are at a much higher risk of recurrence, and serial ctDNA measurements after surgery can help identify patients who may benefit from either escalation or de-escalation of therapies. We are truly excited by these results as they will allow us to more precisely risk-stratify patients with breast cancer in future trials and clinical practice.”

Key findings included:

- ctDNA status after completion of NAT (post-NAT) was highly prognostic for relapse-free survival (RFS).
- Patients with ctDNA detected post-NAT were ~10 times more likely to relapse than patients who were ctDNA negative.
- Detection of ctDNA post-NAT was more predictive of recurrence than pCR.
- Patients who did not have detectable post-NAT ctDNA had excellent outcomes regardless of pathologic response.
- Preliminary analyses indicate that patients who had post-surgical ctDNA detected were >85 times more likely to experience disease recurrence.
- 48% of post-NAT ctDNA detections were <100 PPM, highlighting the importance of NeXT Personal’s ultrasensitive performance.
- Overall, the results suggest that ultrasensitive ctDNA detection in patients with TNBC after completion of NAT and prior to surgery may be used as a prognostic marker, independent of pCR, to guide clinical decision making for additional adjuvant therapies.

Dr. Luc Cabel, MD, PhD, Institut Curie, Paris, presented results from a second study titled “Ultrasensitive circulating tumor DNA (ctDNA) detection for prognostication in triple-negative breast cancer (TNBC) post-neoadjuvant chemotherapy (NAC).” This study included 86 patients with early stage (Stage I-III) TNBC receiving neoadjuvant therapy. Key findings included:

- ctDNA was detected in 100% (84/84) of pretreatment baseline plasma samples.
- The majority of ctDNA detections during NAT (51%) and post-NAT (55%) were in the ultrasensitive range below 100 PPM of ctDNA.
- Post-NAT ctDNA status was highly prognostic. Patients with ctDNA detected post-NAT were ~36 times more likely to have a distant relapse than patients who tested negative.
- For patients who were non-pCR, ctDNA negative patients were 93% less likely to relapse than ctDNA positive patients.
- ctDNA status can be combined with pCR status to assess patient distant relapse risk following NAT.

Said François-Clément Bidard, MD, PhD, one of the Institut Curie lead investigators on the study, “Our results uncover the clinical need for ultrasensitive MRD testing, and pave the way for ctDNA-based adjuvant therapy decisions in early triple negative breast cancer.”

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, clinical relevance or importance of the NeXT Personal test. 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 (including detection earlier than standard of care imaging), monitor or predict a patient’s response to therapy or risk of cancer recurrence, accurately predict clinical outcomes for cancer patients, or impact cancer care or management (including for escalation or de-escalation of treatment), or to the clinical adoption or use of, or the ability of Personalis to obtain Medicare coverage or reimbursement for, the NeXT Personal test, or to the sufficiency of the publication and study results described in this press release to support such adoption, use, coverage or reimbursement. 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’ Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (SEC) on February 27, 2025, and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 6, 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. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. Personalis undertakes no duty to update this information unless required by law.

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Investors:
Caroline Corner
investors@personalis.com
415-202-5678

Media Contact
pr@personalis.com

Source: Personalis, Inc.