



New Publication from ICR and Royal Marsden Researchers Highlights the Importance of Ultra-Sensitive ctDNA Testing for Early-Stage Breast Cancer Recurrence Detection

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FREMONT, Calif.--(BUSINESS WIRE)--Mar. 3, 2025-- [Personalis, Inc.](#) (Nasdaq: PSNL), in collaboration with Professor Nick Turner, Dr. Isaac Garcia-Murillas and their colleagues at The Institute of Cancer Research, London and The Royal Marsden NHS Foundation Trust in the UK, published results from their early-stage breast cancer study in *Annals of Oncology*. In this groundbreaking study, the authors highlight advancements in breast cancer residual disease (MRD) and recurrence detection using NeXT Personal®, an ultra-sensitive personalized test designed to detect small traces of circulating tumor DNA (ctDNA) in the blood of cancer patients and survivors.

The findings of this study highlight the potential for using NeXT Personal in guiding management of breast cancer, currently the most common cancer in the U.S., with an estimated 300,000 new cases and approximately 40,000 deaths forecasted for 2024, according to the U.S. National Cancer Institute (NCI). Personalis' NeXT Personal assay utilizes whole-genome sequencing of the patient's tumor to identify a unique fingerprint of up to ~1,800 variants. A personalized test is then created for the patient that can recognize that fingerprint from a blood sample with ultra-high sensitivity down to ~1 part per million (PPM) of ctDNA.

In this study, NeXT Personal was used to analyze blood samples from a cohort of 78 patients with early-stage breast cancer. The cohort included patients with triple-negative breast cancer (TNBC), HER2+, and HR+ breast cancers. The NeXT Personal test showed high sensitivity for detecting early-stage breast cancer with ~39% of all detections occurring in the ultra-sensitive range below 100 PPM, demonstrating the test's ability to detect exceedingly small traces of cancer in the blood. The test detected 100% of the patients that had breast cancer recurrence, a median of ~15 months and up to 5 years ahead of standard of care radiographic imaging. Importantly, 100% of patients who tested negative with NeXT Personal throughout the study period remained disease-free.

First author, Dr. Isaac Garcia-Murillas, Senior Staff Scientist in the Molecular Oncology Group at The Institute of Cancer Research, London, said, "Most personalised liquid biopsies currently use whole exome sequencing to identify mutations. However, the NeXT Personal approach goes one step further and uses whole genome sequencing to identify up to 1,800 mutations in a patient's tumor DNA that could uniquely identify recurrence of the patient's cancer from a blood sample. NeXT Personal demonstrated the best MRD performance we have seen in this study cohort. With the ultra-sensitive performance of NeXT Personal, we see strong opportunities to impact breast cancer care and management, especially for the escalation and de-escalation of treatment."

"We designed NeXT Personal to detect residual or recurrent cancer in its earliest stages. This study shows the clinical importance of ultra-sensitive ctDNA detection in early-stage breast cancer," said Richard Chen, MD, MS, Chief Medical Officer and Executive Vice President of R&D at Personalis. "With the ability to detect breast cancer recurrence well ahead of standard of care imaging, we can potentially help patients receive treatment sooner for their cancer, or give patients additional peace of mind with a negative test."

Dr. Chen added, "With these exciting results, expanding access to NeXT Personal for breast cancer patients becomes a priority. This landmark publication paves the way toward reimbursement approval for NeXT Personal in early stage 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 from biopsy through the life of the patient. 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](#)).

About the Institute of Cancer Research, London

The Institute of Cancer Research, London, is one of the world's most influential cancer research organisations.

Scientists and clinicians at The Institute of Cancer Research (ICR) are working every day to make a real impact on cancer patients' lives. Through its unique partnership with The Royal Marsden NHS Foundation Trust and 'bench-to-bedside' approach, the ICR is able to create and deliver results in a way that other institutions cannot. Together the two organisations are rated in the

top four centres for cancer research and treatment globally.

The ICR has an outstanding record of achievement dating back more than 100 years. It provided the first convincing evidence that DNA damage is the basic cause of cancer, laying the foundation for the now universally accepted idea that cancer is a genetic disease. Today it is a world leader at identifying cancer-related genes and discovering new targeted drugs for personalised cancer treatment.

The ICR is a charity and relies on support from partner organisations, funders and the general public. A member institution of the University of London, it is one of the UK's leading higher education institutions, placing first for biological sciences and second overall in the definitive 'REF2021' rankings of UK university research quality, impact and environment, and provides postgraduate higher education of international distinction.

The ICR's mission is to make the discoveries that defeat cancer.

For more information visit [ICR.ac.uk](https://www.icr.ac.uk)

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 a patient's response to therapy, 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. 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

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