New Nature Medicine Publication Shows ctDNA Levels Linked to Recurrence Risk in Lung Cancer

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Results demonstrate the importance of ultra-sensitive ctDNA detection in lung cancer

FREMONT, Calif.--(BUSINESS WIRE)--Jan. 13, 2025--(Nasdaq: PSNL), in collaboration with Professor Charles Swanton and his colleagues at London's Francis Crick Institute and University College London, published new results from their TRACERx lung cancer study in Nature Medicine. In this groundbreaking study funded by Cancer Research UK, co-authors Black and Bartha et al. highlight advancements in lung cancer 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.

In this study, NeXT Personal was used to analyze pre-operative blood samples from a TRACERx cohort of 171 patients with early-stage non-small cell lung cancer (NSCLC). The NeXT Personal test showed high sensitivity for detecting early-stage I-III NSCLC pre-operatively, including 100% of non-adenocarcinomas and 81% of lung adenocarcinomas (LUAD), a common subtype that has previously been one of the most challenging to detect in blood samples because of low ctDNA shedding.

The publication also showed ctDNA levels prior to surgery were highly prognostic for overall survival in early-stage LUAD patients. Early-stage LUAD patients who tested negative for ctDNA with NeXT Personal prior to surgery exhibited a 100% 5-year overall survival rate while patients testing positive had a high overall risk of relapse during that same period. Furthermore, patients who tested positive for very low traces of cancer (below 80 PPM of ctDNA) still had a high risk of recurrence, suggesting the importance of ultra-sensitive MRD testing with NeXT Personal. "This study demonstrates the potential of using more sensitive ctDNA tests like NeXT Personal in detecting lung cancer. These tools are important for personalizing care and maximizing the clinical benefit for individual patients," said Dr. Charles Swanton.

"We designed NeXT Personal to detect residual or recurrent cancer in its earliest stages, and this study shows the clinical importance of that ultra-sensitive detection in early-stage lung cancer," said Richard Chen, MD, MS, Chief Medical Officer and Executive Vice President of R&D at Personalis. "We look forward to continuing our work with the TRACERx team on the broader clinical performance of ctDNA testing in early stage lung cancer. We expect the subsequent publication of those results will help support our submission for Medicare coverage of NeXT Personal Dx in lung cancer."

Personalis' NeXT Personal assay utilizes whole-genome sequencing of the patient's tumor to identify a unique signature of up to ~1,800 variants. A personalized blood test is then created for the patient that can recognize that signature with an ultra-high sensitivity down to ~1 PPM of ctDNA. The findings of this study suggest the potential for using NeXT Personal in guiding management of lung cancer, the second most common cancer in the U.S., with an estimated 238,340 new cases and 127,070 deaths in 2023, and high recurrence rates even in early-stage disease.

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 Francis Crick Institute

The Francis Crick Institute is a biomedical discovery institute dedicated to understanding the fundamental biology underlying health and disease. Its work is helping to understand why disease develops and to translate discoveries into new ways to prevent, diagnose and treat illnesses such as cancer, heart disease, stroke, infections, and neurodegenerative diseases.

An independent organisation, its founding partners are the Medical Research Council (MRC), Cancer Research UK, Wellcome, UCL (University College London), Imperial College London and King's College London .

The Crick was formed in 2015, and in 2016 it moved into a brand new state-of-the-art building in central London which brings together 1500 scientists and support staff working collaboratively across disciplines, making it the biggest biomedical research facility under a single roof in Europe.

http://crick.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 or clinical relevance 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, monitor a patient’s response to therapy or more accurately predict clinical outcomes for cancer patients, or to the clinical adoption or use of, or the ability of Personalis to submit for or obtain Medicare coverage or reimbursement for, the NeXT Personal test. 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, 2023, filed with the Securities and Exchange Commission (SEC) on February 28, 2024, as updated by Personalis’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 8, 2024, Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 7, 2024, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 6, 2024. 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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