Analysis from TRACERx Study Reveals More Sensitive and Earlier ctDNA Detection in Lung Cancer Patients by Personalis' MRD Technology

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NeXT Personal® ctDNA assay shown to be more sensitive and predictive of clinical outcomes in early-stage lung cancer patients

Demonstrates importance of an ultra-sensitive ctDNA approach

FREMONT, Calif.--(BUSINESS WIRE)--Oct. 21, 2023--Personalis, Inc. (Nasdaq: PSNL), a leader in precision oncology, today announced the presentation of initial findings from its work with the groundbreaking TRACERx lung cancer study, marking a substantial advancement in lung cancer circulating tumor DNA (ctDNA) detection and management. The Personalis NeXT Personal cancer assay, created to detect and monitor residual and recurrent disease (MRD), demonstrated significantly improved detection rates for early-stage lung cancer, including lung adenocarcinoma (LUAD), one of the most common and challenging subtypes of non-small cell lung cancer (NSCLC) to identify in blood samples.

The findings come from an analysis by Professor Charles Swanton, Dr. James Black, and other members of the TRACERx consortium, renowned for their work on the complexities of cancer genomics. The findings were presented by Dr. Black at the 2023 European Society for Medical Oncology (ESMO) Congress on October 21 in Madrid, Spain, and are the first publicly presented results from Personalis' collaboration with Cancer Research UK's Cancer Research Horizons, University College London (UCL), and the Francis Crick Institute.

Lung cancer is the second most common cancer in the U.S., with an estimated 238,000 new cases and approximately 127,000 deaths forecasted for 2023. The current standard of care for relapse detection of NSCLC, the most common type of lung cancer, is primarily focused on imaging modalities such as CT scans, which are known to be limited in sensitivity. This ongoing collaboration is focused on addressing this challenge through advanced ctDNA analysis. For the current analysis, the teams used NeXT Personal to identify and track MRD in over 170 patients from the TRACERx cohort.

Higher sensitivity for early-stage lung cancer

In this analysis, NeXT Personal showed significantly higher sensitivity in early-stage NSCLC patients compared to two previous publications on the TRACERx cohort. Pre-surgery, the assay demonstrated 100% sensitivity for ctDNA in pre-surgical non-LUAD samples and 81% pre-surgical ctDNA sensitivity for LUAD, one of the most common types of lung cancer but also one of the most challenging to detect in blood. The pre-surgical sensitivity for early-stage LUAD was up to 4X higher than in previous studies on the TRACERx cohort, depending on stage. This high sensitivity enhanced the assay's ability to detect recurrence and monitor lung cancer effectively.

Ability to identify low and high recurrence risk prior to surgery

The study demonstrated that pre-surgical ctDNA levels with NeXT Personal could be used to classify early-stage lung cancer patients into lower- and higher-recurrence risk groups. Furthermore, the analysis showed that the ultra-low levels of ctDNA detection enabled by NeXT Personal were critical to determining patient recurrence risk. For example, LUAD patients who were ctDNA-negative before surgery with NeXT Personal strikingly exhibited a 100% 5-year overall survival rate and 94% relapse-free survival rate in the TRACERx cohort. In comparison, patients who were ctDNA-positive prior to surgery had a high risk of cancer recurrence over 5 years.

Earlier detection for earlier potential intervention

The results presented at ESMO also showed that NeXT Personal enabled earlier detection of residual or recurrent lung cancer after surgery in the TRACERx cohort. The results show a median lead time of approximately 6 to 11 months for ctDNA detection ahead of traditional imaging, and significantly longer than previous TRACERx results. The ability to identify potential recurrence months earlier offers the possibility to intervene and accelerate treatment in high-risk patients.

The promise of helping lung cancer patients throughout their journey

Overall, the TRACERx results raise the potential of using NeXT Personal to help inform patient management throughout the patient journey, from pre-surgery to post-surgery and longer-term monitoring.

"Existing tests for lung cancer patients often fall short in detecting residual or recurrent cancer early. Our NeXT Personal test is designed to change that by being significantly more sensitive. We are thrilled that the TRACERx results presented at ESMO demonstrated higher sensitivity for the most common types of early-stage lung cancer, including the most challenging subtypes. That sensitivity translated into a better understanding of recurrence risk for patients, and earlier detection of recurrence. We hope that earlier detection can ultimately be life-saving, offering patients a greater chance at successful treatment," said Richard Chen, MD, MS, Chief Medical Officer and Executive Vice President, R&D of Personalis.

The NeXT Personal technology leverages whole genome sequencing and advanced noise suppression with NeXT SENSE™ technology to identify a unique genetic signature derived from a patient's tumor based on up to ~1,800 variants. This unique signature is tracked in the patient's blood over time to find residual or recurrent cancer, achieving an industry-leading sensitivity of down to ~1 PPM. This enhanced sensitivity offers the potential for earlier recurrence risk assessment and intervention, earlier detection, more precise monitoring, and substantial advancement in lung cancer care.

"Patients often live in fear of undetected cancer leading to a relapse. Our new assay is a transformative leap forward—it's like turning on a spotlight in a previously dark room. It finds what other tests often miss, providing a new level of certainty and peace of mind. This isn't just about technology; it's about giving patients and their families a clearer path forward in their fight against cancer," said Chris Hall, President and CEO of Personalis.

Webcast and Conference Call Information

Personalis will host a conference call on Tuesday, October 24, 2023 at 6:00 a.m. Pacific Time / 9:00 p.m. Eastern Time. The live webinar, which includes presentation slides, can be accessed here, or at https://investors.personalis.com. A replay of the webinar will be available shortly after the conclusion of the call and will be archived on the company's website.

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).

Personalis 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 attributes or advantages of NeXT Personal. 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 Personalis’ ability to demonstrate attributes or advantages of NeXT Personal or the Personalis NeXT Platform. 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, 2022, filed with the Securities and Exchange Commission (SEC) on February 23, 2023, and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023. 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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