Personalis Announces Publication Validating NeXT Personal® Test for Ultra-sensitive MRD Detection and Cancer Treatment Response Monitoring

March 26, 2024

Blood-based assay uses personalized tumor-informed approach designed to detect cancer recurrence early with an ultra-sensitive approach

FREMONT, Calif.--(BUSINESS WIRE)--Mar. 26, 2024--Personalis, Inc.(Nasdaq: PSNL), a leader in advanced genomics for precision oncology, today announced a new publication validating the company's NeXT Personal test, an ultra-sensitive, tumor-informed circulating tumor DNA (ctDNA) assay. NeXT Personal is designed to help detect minimal residual disease (MRD), monitor therapy response, and identify recurrence with high analytical sensitivity and accuracy, enhancing the decision-making process and ultimately improving patient outcomes in the ongoing battle against cancer.

"The robust validation results in this publication provide a foundational building block towards achieving Medicare coverage for NeXT Personal," said Richard Chen, MD, MS, Chief Medical Officer and Executive Vice President, R&D of Personalis. "We are laser-focused on developing and publishing data to establish NeXT Personal as a leading MRD test."

In the analytical validation study published in *Oncotarget*, scientists from Personalis evaluated NeXT Personal by testing samples from over 120 patients across nine cancer types and paired tumor and normal cell lines. The NeXT Personal technology leverages whole genome sequencing (WGS) 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. Through NeXT Personal, a custom panel is created to detect trace amounts of ctDNA from patient blood samples.

The analytical range measurements demonstrated a detection threshold of 1.67 parts per million (PPM) of ctDNA with a LOD_{95} of 3.45 PPM, highlighting NeXT Personal's ultra-high analytical sensitivity. Results of the study showed 100% measured analytical specificity, with a confidence interval spanning 99.92 to 100%.

"We designed NeXT Personal to enable another big leap in ctDNA sensitivity and specificity," said Chen. "Taken together, the results show NeXT Personal's capability for ultra-sensitive detection of ctDNA in patient plasma samples and the test's potential to reliably inform clinicians and patients on residual cancer, cancer treatment response, and cancer recurrence through ctDNA detection, earlier than conventional detection approaches," Chen noted.

At the 2023 European Society for Medical Oncology (ESMO) Congress, initial findings showed that NeXT Personal's significantly improved detection rates could translate into clinical benefit in 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. This data from the TRACERx Study demonstrated the assay was able to find cancer nearly a year ahead of imaging and was predictive of clinical outcomes in early-stage lung cancer patients.

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 the 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

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 the NeXT Personal assay, the potential achievement of Medicare coverage for NeXT Personal, the expected adoption of NeXT Personal in the clinical market, the ability of NeXT Personal to inform or enhance clinical decision-making or to improve or predict patient outcomes, or other future events. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from any anticipated results or expectations expressed or implied by such statements. Factors that could materially affect actual results can be found in Personalis' filings with the U.S. Securities and Exchange Commission, including Personalis' most recent reports on Forms 8-K, 10-K and 10-Q, and include those listed under the caption "Risk Factors." Personalis disclaims any obligation to update such forward-looking statements.

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Source: Personalis, Inc.