

Personalis Launches NeXT Personal® Dx for Early Access Clinical Use in Residual Disease and Recurrence Detection in Cancer

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- NeXT Personal Dx is an ultra-sensitive test for detecting cancer from a blood sample
- Clinical data from groundbreaking TRACERx lung cancer study demonstrates significant sensitivity and lead time improvements in detecting cancer

FREMONT, Calif.--(BUSINESS WIRE)--Oct. 26, 2023-- Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for precision oncology, announced today the launch of the Early Access Program for NeXT Personal Dx, a tumor-informed, whole genome-based liquid biopsy laboratory developed test (LDT) for detection of molecular residual disease (MRD) and recurrence in cancer. Designed to help oncologists detect cancer recurrence earlier and aid in treatment decision-making, NeXT Personal Dx is poised to reshape the clinical use of MRD testing by delivering unmatched sensitivity down to the level of one circulating tumor DNA (ctDNA) molecule in a million.

"Our ultra-sensitive NeXT Personal Dx test has the ability to reveal previously hidden traces of residual cancer, helping to reduce uncertainty for physicians and patients," said Chris Hall, President and CEO of Personalis. "We're excited to work with oncologists through this Early Access Program to detect cancer even earlier and increase confidence in clinical decisions. We have several MDs that have expressed interest and we are already receiving samples."

NeXT Personal Dx features:

- Unprecedented sensitivity and specificity: Industry-leading analytical sensitivity, detecting down to ~1 PPM (parts per million) or 1x10⁻⁶ tumor fraction and >99.9% analytical specificity
- Whole genome-based tumor-informed assay: Selects up to 1,800 variants to design a highly sensitive and specific personalized tumor signature for each patient
- NeXT SENSE™ technology Proprietary Signal Enhancement and Noise Suppression Engine that, together with the personalized tumor signature, enables ultra-sensitive detection

The NeXT Personal Dx test is currently available through an Early Access Program to a limited number of clinical customers as the company builds clinical evidence and achieves Medicare reimbursement. The EAP will enable oncologists to access NeXT Personal Dx for clinical use, with a focus on lung cancer, breast cancer, and immunotherapy response monitoring.

Personalis also recently announced data from the groundbreaking TRACERx study investigating the use of NeXT Personal in early-stage lung cancer for MRD and recurrence detection. Personalis, along with collaborators from Cancer Research UK's Cancer Research Horizons, University College London (UCL), and the Francis Crick Institute, presented data at the 2023 European Society for Medical Oncology (ESMO) Congress showing the ability of NeXT Personal to detect lung cancer more sensitively and identify cancer recurrence with a median lead time of approximately 6 to 11 months ahead of traditional imaging, and significantly longer than previous TRACERx results.

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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