ASCO Data Highlights NeXT Personal® Ultra-sensitive MRD Performance in Early-stage Breast Cancer Recurrence Detection and Immunotherapy Monitoring

June 4, 2024

Personalis will host a webinar call on June 19th, 2024 at 1:00 p.m. Pacific Time / 4:00 p.m. Eastern Time to present ASCO highlights from the conference

FREMONT, Calif.--(BUSINESS WIRE)--Jun. 4, 2024--Personalis, Inc. (Nasdaq: PSNL) announced today that data presented at the American Society for Clinical Oncology (ASCO) oral podium talks in Chicago, IL demonstrated that the Personalis NeXT Personal test had exceptional detection rates and performance for early-stage breast cancer and immunotherapy monitoring. The NeXT Personal test is the first of a new class of ultra-sensitive liquid biopsy tests designed to detect the earliest traces of cancer recurrence and monitor a patient's response to therapy. The test can detect circulating tumor DNA (ctDNA) down to an ultra-sensitive range (<100 parts per million of ctDNA) and the data presented as ASCO highlights the clinical importance of this approach.

Earlier and more sensitive detection of recurrence in early-stage breast cancer

Breast cancer is 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). The current standard of care for relapse detection of breast cancer is primarily imaging such as mammography, which can have limited sensitivity. These studies are focused on addressing this challenge through advanced ctDNA analysis with NeXT Personal.

Breast cancer results were presented in an oral presentation by Dr. Isaac Garcia-Murillas and come from a team at the Institute of Cancer Research, London and Royal Marsden NHS Foundation Trust in the UK led by Professor Nicholas Turner, renowned for his work on the use of ctDNA to guide breast cancer treatment. In this study, they found:

- NeXT Personal's Ultra-sensitive range enabled earlier detection of recurrence, with a median ~15-month lead time over imaging detection
- 100% of patients that recurred were detected with NeXT Personal and 100% of patients that were ctDNA negative on longitudinal testing were cancer-free
- NeXT Personal enabled detection of very low traces of cancer, with ~39% of all detections falling in the ultra-sensitive range below 100 PPM (below 0.01% of ctDNA)
- NeXT Personal enabled substantially better sensitivity and lead times compared to other MRD assays on the same patient cohort

Dr. Garcia-Murillas noted, "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."

Additional breast cancer results presented at ASCO include a poster presentation by Dr. Adrienne Waks at the Dana Farber Cancer Institute using NeXT Personal to assess neoadjuvant therapy response in the DAPHNe HER2+ breast cancer trial. In this study, NeXT Personal demonstrated high baseline sensitivity (92%) for ctDNA for HER2+ breast cancer patients enabled by the ultra-sensitivity of the test with 27% of detections in the ultra-sensitive range. NeXT Personal was also able to demonstrate neoadjuvant THP treatment effectiveness by showing the treatment had cleared the tumor MRD.

Strong performance in immunotherapy monitoring

Several hundred thousand cancer patients are put on immunotherapy treatment annually. While over 40% of patients with cancer are eligible for immunotherapy, only ~12% of patients respond, underscoring the need for a blood test that monitors treatment response for patients, doctors, and payers.

An oral presentation showed the importance of NeXT Personal's use for immunotherapy monitoring. Dr. Rodrigo Toledo at the Vall d'Hebron Institute of Oncology (VHIO) presented data in an oral presentation that demonstrated that the baseline levels and the changes in levels of ctDNA detected by NeXT Personal are highly predictive of therapy response and clinical outcomes for late-stage cancer patients receiving immunotherapy. This includes the finding that patients who had a significant decrease in ctDNA levels from baseline to the third cycle of immunotherapy had overall survival that was more than two times longer than those who did not. They also demonstrated that NeXT Personal had an average lead time for detecting progression of 81 days over imaging.

The VHIO data is a broad study that included patients across 18 different solid tumor types. "The changes in ctDNA levels elucidated by the NeXT Personal test can dramatically enhance our ability to understand if late-stage cancer patients are responding to their therapy. This is critical to optimally managing immunotherapy and other treatments for these very sick patients," said Dr. Toledo.

Additional results presented at ASCO include a poster presentation by Professor Andy Nixon at the Duke Cancer Institute in late-stage esophagogastric cancer that received immunotherapy in combination with chemotherapy as part of the KeyLargo trial. In this study, Dr. Nixon found that ctDNA levels were demonstrated to be highly prognostic for therapy response. In late-stage cancer patients, ctDNA levels can be very low with ~20% of samples falling in the ultra-sensitive range, underscoring the importance of an ultra-sensitive test like NeXT Personal.

“With the addition of the ASCO data, we now have presented data across lung cancer, breast cancer, and patients on immunotherapy that consistently highlight the importance of an ultra-sensitive MRD platform like NeXT Personal to detect recurrence earlier, monitor therapy response, and more accurately predict clinical outcomes for cancer patients,” said Dr. Richard Chen, Chief Medical Officer and EVP of R&D at Personalis. “We also expect the strong performance in these studies will help drive clinical adoption and reimbursement of NeXT Personal.”

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Webcast and Conference Call Information

To receive the dial-in instructions, please email investors@personalis.com.

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 time points, 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

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 cancer recurrence early, monitor a patient’s response to therapy or more accurately predict clinical outcomes for cancer patients, or the clinical adoption or use of, 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, and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 8, 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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Investors:
Caroline Corner
investors@personalis.com
415-202-5678

Media:
pr@personalis.com

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