Personalis Announces Two Abstracts Accepted for Presentation at ASCO 2023

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New findings emphasize the potential of company's ultra-sensitive MRD platform for longitudinal disease monitoring and the study of dynamic tumor evolution

FREMONT, Calif.--(BUSINESS WIRE)--May 30, 2023--Personalis, Inc. (Nasdaq: PSNL) today announced it will present new clinical data as scientific posters at the American Society of Clinical Oncology (ASCO) Annual Meeting 2023, which convenes from June 2-6, 2023, in Chicago, Ill.

Among many applications, clinicians and researchers are increasingly interested in the use of ctDNA to monitor immune checkpoint inhibitor (ICI) therapy response. Though ICIs can be extremely effective at treating certain forms of cancer, only a subset of patients will respond. Even when there's an initial response, the development of resistance can lead to relapse.

"Monitoring patient response to ICI therapy using current technologies is often limited in scope and resolution," explains Christopher Hall, Chief Executive Officer and President at Personalis. "Ultra-sensitive ctDNA detection may allow near-real-time data on tumor therapeutic response and evolution, ultimately with the hope of guiding treatment decisions at critical timepoints."

Progress in the field has thus far been limited due to the significant technical challenge of detecting the low levels of ctDNA that may exist during and after curative treatment.

At ASCO, Personalis will present data from two retrospective clinical studies that demonstrate a breakthrough in ctDNA detection sensitivity. "We've developed NeXT Personal® with the express goal of ultra-sensitive detection of ctDNA during and after treatment, as well as enabling personalized care throughout the patient's journey," says Hall.

NeXT Personal's industry-leading sensitivity is recognized by leading experts in the oncology domain—such as Andy Nixon, Ph.D., from Duke Cancer Institute and Klaus Pantel, MD, Ph.D., from the University Medical Centre Hamburg-Eppendorf—who have begun to adopt this technology. Data from these collaborations will be presented at ASCO, demonstrating the ultra-high sensitivity of NeXT Personal and its potential utility in monitoring tumor response to ICI. Specifically, the studies demonstrate that:

- ctDNA levels during treatment correlate with therapy response, as defined by RECIST v1.1
- ctDNA clearance, as determined by NeXT Personal, is predictive of patient survival in both melanoma and gastric cancer cohorts
- Across both gastric and melanoma cohorts, NeXT Personal detected ctDNA fragments in quantities ranging from >300,000 down to as low as 2.3 PPM; with a median LOD of 1.97 PPM
- Nearly a third of melanoma patients presented with ctDNA levels below 100 parts per million (PPM), which likely would have been missed by other available minimal residual disease (MRD) assays
- NeXT Personal successfully detected the evolution of therapeutically relevant variants during treatment.

Collectively, these posters represent the latest in a growing body of evidence indicating that ultra-sensitive ctDNA detection is needed to bring higher resolution, and more personalized care to patients with cancer, both during treatment and after.

Details of the Personalis abstracts are outlined below, and further details about the poster presentations can be found here.

Poster details

Title: Ultra-sensitive, tumor-informed ctDNA profiling in patients with gastroesophageal cancer and treated with pembrolizumab and longitudinal ctDNA kinetics.
Overview: In collaboration with Duke Cancer Institute and the University of North Carolina, samples from a phase II clinical trial (NCT03342937) involving patients with metastatic esophagogastric cancer were tested using Personalis' NeXT Personal platform to assess ctDNA levels and their utility for longitudinal disease monitoring and surveillance of dynamic tumor evolution. We found that ctDNA levels dynamically varied from 5.3 to 302,000 PPM, with NeXT Personal showing an ultra-sensitive limit of detection between 1.5 and 4.6 PPM. Results showed that a reduction in ctDNA during treatment corresponded with better outcomes. And, ctDNA analysis revealed the evolution of a potentially therapeutically relevant variant in one patient during treatment.

Title: Association of ultra-sensitive ctDNA assay to identify actionable variants and response to immune checkpoint inhibitor (ICI) therapy in metastatic melanoma.
Overview: Detection of MRD via ctDNA can identify therapeutic response/resistance months in advance of imaging, and monitoring clinically actionable variant dynamics in ctDNA may be important for guiding treatment. However, efforts to use ctDNA have been hindered by low sensitivity, with most assays having a limit of detection of ~100 PPM. In this study, we collaborated with the University Medical Centre Hamburg-Eppendorf. Samples collected from melanoma patients receiving ICI were collected over several years and, using NeXT Personal, ctDNA findings were correlated with clinical outcomes. Levels of ctDNA ranged from 2.3-100,000 PPM, with NeXT Personal showing an ultra-sensitive limit of detection of 1.97 PPM. Importantly, 37% of detections were below 100 PPM. In response to ICI, average ctDNA levels fell more than 3-fold and the frequency of multiple therapeutically relevant variants changed, such that tumors appeared less sensitive to ICI.

About Personalis

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 Twitter.

Personalis 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 NeXT Personal or other Personalis assays, the sensitivity of NeXT Personal or its potential utility in monitoring tumor therapeutic response or evolution, 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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