Personalis Announces Four Abstracts Accepted for Presentation at AACR Annual Meeting 2023

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New findings reinforce potential of company's highly-sensitive MRD offerings for earlier recurrence detection and therapy response monitoring

FREMONT, Calif.--(BUSINESS WIRE)--Mar. 22, 2023--Personalis, Inc. (Nasdaq: PSNL) today announced it is presenting new research data as scientific posters at the American Association for Cancer Research (AACR) Annual Meeting 2023, which convenes from April 14-19, 2023 in Orlando, Florida.

The data highlights the power of the company's highly-discerning technologies that both characterize and monitor cancer, including initial research findings from a collaboration with University Medical Center Hamburg-Eppendorf (UKE) and its new Fleur-Hiege Center for Skin Cancer Research, where Dr. Klaus Pantel, Dr. Christoffer Gebhardt, and team are using NeXT Personal® to track tumor response to immunotherapy (IO) in patients with melanoma, with the aim of gathering evidence to advance the use of ultra-sensitive minimal residual disease (MRD) detection in routine clinical practice for IO therapy monitoring.

"We are encouraged by initial findings from our research with Dr. Pantel and his team at UKE, which show that highly sensitive detection of circulating tumor DNA (ctDNA) may improve our ability to predict responses or resistance to therapy earlier than imaging," said Sean Boyle, Executive Director of Scientific Applications at Personalis. "Our deep expertise in genomic sequencing and commitment to scientific excellence have laid the foundation not only for our own MRD advancements, but also for exceptional partnerships with leaders in the field of oncology."

Boyle added, "We are also excited to share updates on NeXT Personal performance, with research data that shows the highly sensitive assay can detect MRD even in challenging samples, at earlier time points. The addition of clinically relevant tumor-agnostic actionable content makes NeXT Personal unique in its ability to both detect MRD and identify clinically relevant mutations that may be missed with other assays."

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

Title: Ultra-sensitive tumor-informed ctDNA assay predicts survival in advanced melanoma patients treated with immune checkpoint inhibition
Overview: Immune checkpoint inhibition (ICI) elicits clinical benefit in a subset of cancer patients, and monitoring of ctDNA in peripheral blood might improve our ability to predict responses or resistance earlier than imaging. In this study, we analyzed melanoma patients receiving ICI over several years using NeXT Personal, a novel tumor-informed ctDNA platform, and correlated the findings to clinical outcome. Patients that attained ctDNA clearance at one or more plasma timepoints had significantly longer overall survival (OS) and patients with increasing ctDNA levels over the first 25 (or 50) days compared to baseline had significantly reduced OS ($p < 0.05$). Results demonstrate the ultra-high sensitivity for ctDNA with a wide dynamic range of detections, and include *de novo* detection of emerging clinically actionable and resistance variants.

Title: Analytical performance of an ultra-sensitive, tumor-informed liquid biopsy platform for molecular residual disease detection and clinical guidance
Overview: Here we report a performance update of the NeXT Personal platform. Most ctDNA-based MRD detection methods leverage a limited genomic footprint, restricting detection sensitivity and thus their utility in many clinical settings. For example, early-stage, low tumor mutational burden (TMB) cancers may lack sufficient variants in these limited footprints to produce detectable signals. Further, insights into tumor evolution, including actionable mutations may be missed. Utilizing whole genome sequencing of tumor and normal DNA to guide design of bespoke MRD assays, we select up to 1800 high signal, low noise MRD targets and up to 400 exonic variants. Along with proprietary algorithms, this achieves high MRD sensitivity with a limit of detection of 1 ~ 3 parts per million. Additionally, specificity was demonstrated, showing variant detection is > 99.99% with 100% PPV, while individual variant content demonstrates high sensitivity at allele fractions of 0.1% and above, with high accuracy and signal linearity as confirmed by ddPCR ($R2 = 0.998$). Finally, to explore the utility of NeXT Personal in a clinical setting, a retrospective analysis was undertaken in an advanced liver cancer (low TMB). Our data demonstrate high analytical performance of the NeXT Personal platform in both MRD and individual variant detection.

Title: Utilizing response in immune checkpoint inhibitor treated cohorts improves clinical applicability of neoantigen immunogenicity predictions
Overview: Neoantigen-based biomarkers have improved predictions of response to immune checkpoint blockade (ICB) therapy, highlighting the importance of accurate prediction of immunogenic neoantigen candidates. In this study, we deployed a novel approach to optimize prediction models of immunogenic neoantigens using a meta-analysis framework based on multiple ICB cohorts, totaling over 500 patients. Through iterations of SHERPA-Immunogenicity (SI) models, we aggregated pMHC predictions

into patient-specific scores based on the most immunogenic peptide present (SHERPA-Immunogenicity Maximum - SIM) or the quantity of immunogenic peptides identified (SHERPA-Immunogenicity Burden - SIB). We observed that responders had higher SIM and SIB scores compared to non-responders across the melanoma training cohorts, and that SIM scores outperformed SIB scores, suggesting the degree of epitope immunogenicity may be a critical factor in predicting response.

Title: Immune infiltrate co-occurrence and neoantigen similarity are prognostic factors in early stage NSCLC
Overview: By leveraging a comprehensive individual portrait of each patient's immune system, potential novel mechanisms associated with tumor relapse in early-stage NSCLC may be identified. We profiled 11 non-relapsed lung adenocarcinoma (LUAD) patients and 11 covariate-matched (gender, age, stage) relapsed patients, who underwent curative treatment in stage IA-IIIB disease. In this pilot cohort, we used ImmunoID NeXT® to broadly characterize both the tumor and immune system, enabling identification of relapse-associated neoantigens that may share universal features which enhance HLA binding. Relapses in early-stage LUAD patients were associated with neoantigens with lower immunogenicity and an immunosuppressive tumor microenvironment (TME). These findings demonstrate that deeper profiling of shared neoantigen features has the potential to become an early biomarker of relapse, informing patient therapy selection and surveillance.

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.

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 Personalis’ technologies, including NeXT Personal and ImmunoID NeXT, the expected benefits of Personalis’ collaboration with UKE, the performance of NeXT Personal, including sensitivity, specificity or the ability of NeXT Personal to detect MRD or identify clinically relevant mutations in challenging samples or at earlier time points than other methods, 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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Investor Relations:
Caroline Corner
investors@personalis.com
415-202-5678

Media:
Jennifer Temple
pr@personalis.com
650-752-1300

Source: Personalis, Inc.