

Personalis and UCSF to Study Clinical Utility of ctDNA for Treatment Response in Colorectal Cancer

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MENLO PARK, Calif. & SAN FRANCISCO--(BUSINESS WIRE)--Nov. 30, 2022--Personalis, Inc. (Nasdaq: PSNL) today announced a collaboration with UC San Francisco (UCSF) that will deploy a personalized liquid biopsy-based research use only (RUO) assay for a study of patients with colorectal cancer. The research efforts will use Personalis' NeXT Personal Mexical States associated with treatment response and adverse events in a cohort of late-stage colorectal cancer patients receiving *capecitabine* together with pembrolizumab and bevacizumab.

Colorectal cancer is among the top five most prevalent and deadly malignancies worldwide. The efficacy of combined targeted therapy approaches varies widely, reflecting the need for more sophisticated predictive measures. Typical ctDNA assays in use today lack sufficient sensitivity for detecting cfDNA-based biomarkers due to extensive disease heterogeneity, potentially low levels of signal from small metastases, and the wide range of mutational profiles relevant to different types of cancer.

"Assessment of early response and adaptive resistance both critically require a non-invasive liquid biopsy-based assay that can confidently detect changes in the abundance and mutational profile of cancer cells. Through serial monitoring of ctDNA, we will develop greater understanding of patient response to therapy and use these data to inform the development of signatures predictive of response," said Lawrence Fong, MD, the Efim Guzik Distinguished Professor in Cancer Biology at UCSF and leader of the Cancer Immunotherapy Program.

"The increased sensitivity of NeXT Personal will make it possible to identify complete response/absence of disease and recurrence earlier than existing technologies. Further, by leveraging the plasma sampling in this cohort, we aim to determine optimal sample collection timing for early identification of complete response and demonstrate clinical utility. Additionally, we seek to demonstrate earlier detection of disease recurrence, providing support for future interventional studies that can use this information to make rapid changes to treatment," said Richard Chen, MD, Chief Medical Officer and Senior Vice President of R&D at Personalis.

About NeXT Personal

NeXT Personal is a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. The assay is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. It leverages whole genome sequencing of a patient's tumor to identify up to 1,800 specially selected somatic variants that are subsequently used to create a personalized liquid biopsy panel for each patient. This may enable earlier detection across a broader variety of cancers and stages, including typically challenging early-stage, low mutational burden, and low-shedding cancers. NeXT Personal is also designed to simultaneously detect and quantify clinically relevant mutations in ctDNA that may be used in the future to help guide therapy when cancer is detected. These include known targetable cancer mutations, drug resistance mutations, and new variants that can emerge and change over time, especially under therapeutic pressure.

About Personalis

Personalis, Inc. is a leader in advanced cancer genomics, enabling the next generation of precision cancer therapies and diagnostics. The Personalis NeXT Platform® is designed to adapt to the complex and evolving understanding of cancer, providing its biopharmaceutical customers and clinicians with information on all of the approximately 20,000 human genes, together with the immune system, from a single sample. To enable cancer sequencing, Personalis' Clinical Laboratory was built with a focus on clinical accuracy, quality, big data, scale and efficiency. The laboratory is GxP-aligned as well as Clinical Laboratory Improvement Amendments of 1988-certified and College of American Pathologists-accredited. For more information, visit the Personalis website and follow Personalis on LinkedIn and Twitter.

UC Disclaimer

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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 the NeXT Platform, expected benefits of the company's collaboration with UCSF, expected performance or adoption of the NeXT Personal assay, Personalis' business opportunities, leadership, plans or expectations, 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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