Personalis Launches NeXT Personal™, A Tumor-Informed Liquid Biopsy Assay for MRD and Recurrence Detection With Part-Per-Million Sensitivity

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MENLO PARK, Calif.--(BUSINESS WIRE)--Dec. 16, 2021--Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for cancer, today announced the launch of NeXT Personal, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify molecular residual disease (MRD) and recurrence in patients previously diagnosed with cancer. NeXT Personal delivers industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. This enables earlier detection across a broader variety of cancers and stages, including typically challenging early stage, low mutational burden, and low-shedding cancers.

NeXT Personal 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. The targeted panel is then used to sequence millions of unique DNA molecules from a patient's blood sample. Aggregation of signal across these sequences using proprietary algorithms enables part-per-million sensitivity. Personalis' innovative methods are covered by its broad range of early and subsequent intellectual property filings.

Going beyond other tumor-informed MRD assays, NeXT Personal also simultaneously detects and quantifies clinically relevant mutations in circulating tumor DNA (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 which can emerge and change over time, especially under therapeutic pressure.

"With this launch, Personalis is extending what an MRD product can deliver," said John West, Personalis' Chief Executive Officer. "With its dramatic increase in sensitivity, we expect to address a range of tumors which were out of reach with earlier technologies. With its broader information content, we also go beyond detection of a tumor, to provide the additional characterization needed to understand and eventually help manage disease."

"NeXT Personal addresses the need for higher sensitivity assays, opening the door for earlier detection and more sensitive monitoring of patient response to therapy across a broader range of cancers and stages. Today's release is targeted towards biopharma partners and clinical collaborators. In 2022, we plan to release NeXT Personal as a clinical test, which we expect will yield opportunities for earlier intervention and treatment for cancer patients," said Dr. Richard Chen, Personalis' Chief Medical Officer and SVP of R&D.

About Personalis

Personalis, Inc. is a leader in advanced cancer genomics for 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 tissue sample. In population sequencing, Personalis operates one of the largest sequencing operations globally and is currently the sole sequencing provider to Veterans Affairs' Million Veteran Program. To enable cancer and population 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 www.personalis.com and follow Personalis 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 NeXT Personal or the Personalis NeXT Platform, Personalis' business opportunities, leadership, plans or expectations, the coverage or breadth of the company's intellectual property, or other future events. Such forward-looking statements involve risks and uncertainties, including those related to the COVID-19 pandemic, 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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