Personalis Announces Expansion of Its Patent Portfolio Related to Tumor-Informed Detection of Molecular Residual Disease

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MENLO PARK, Calif.--(BUSINESS WIRE)--Jul. 12, 2022--Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for cancer, has added another patent family to its molecular residual disease (MRD)-related IP portfolio, with priority to January 2013. US Patent No. 11,384,394 describes the detection of MRD and recurrence by using whole genome sequencing of a patient's tumor to identify variants for a personalized liquid biopsy assay.

As with recently issued US Patent 11,299,783, the '394 patent covers many elements of Personalis' NeXT Personal™ platform, including that it describes a highly sensitive measurement of tumor burden with simultaneous tracking of up to thousands of tumor variants, both tumor-informed and prespecified, in a single panel design. Prespecified variants from a database may be used to identify resistance to a tumor therapy, or the emergence of a second, unrelated tumor.

Tumors can be detected by the DNA they shed into a patient's blood plasma, but the amount of that DNA can be very low. After a tumor has been surgically resected, it may be present at just a few parts per million. At that level, most parts of the tumor genome are not present in a plasma sample. To improve the chances of detecting a signal, data can be combined from several tumor mutation positions in a genome. Since the position of these mutations is not stereotypical in most cancers and appear in different positions across the genome for each patient's tumor, using an older, tumor-agnostic (fixed panel) approach to cancer sequencing wastes up to 99.9% of sequence reads because they cover parts of the genome where that patient's tumor does not have a mutation. If, instead, a patient's tumor is sequenced once to identify where a patient's mutations are on the genome, a custom assay can then view just those positions whenever a blood sample needs to be analyzed.

By eliminating wasted sequencing, it also becomes practical to sequence deeply enough to identify even minute tumor signals. This is called a tumor-informed approach. To identify the slightest trace of cancer, Personalis' NeXT Personal looks for the fingerprint of each tumor (its mutations) at almost two thousand places across the genome. Most tumors have that many mutations, but only a few percent are in the coding regions of the genome, where an exome could capture them. To find thousands of mutations, most tumors, particularly those from breast and prostate cancers, which have low mutational burden, whole genome sequencing is needed. Personalis has pioneered this approach, and using it, the NeXT Personal platform can detect tumors in blood plasma down to a few parts per million, or below. In many cases this increase in sensitivity could allow recurrence to be detected much earlier when there may be better therapeutic options.

With the issuance of the '394 patent, Personalis now has 21 issued US and foreign patents, spanning 16 distinct families, relating to advanced genomic sequencing and analysis solutions. In addition, the company has over 30 pending US and foreign patent applications that relate to its existing advanced cancer detection platforms and novel research areas, including methods for interpreting genetic data generated by its platforms.

John West, CEO and co-founder of Personalis, and a co-inventor, said, "Personalis was active in whole human genome sequencing very early on. Our first publication, in 2011[(1)], pioneered methods for whole genome sequence analysis, and by 2012 we had received our first customer order for the sequencing and analysis of over 1,000 human genomes. By 2013, when we filed this patent, we had also pioneered methods for advanced targeted sequencing[(2)] and realized how powerful it could be to use them together. NeXT Personal is our most recent product leveraging the combination, and we believe that it can be transformational in cancer, detecting residual disease and recurrence, and in actively fighting cancer after recurrence has been detected. The issuance of this newest patent from one of our earliest patent families further validates our early vision to provide our customers, partners, and patients with the best possible information regarding an individual's tumor."

Since 2012, Personalis has sequenced over 150,000 human genomes. In 2019 the company launched whole genome tumor sequencing as a service, and in 2021 it launched NeXT Personal for the highly sensitive detection of MRD, based on a whole genome tumor-informed approach.

References

(1) "Phased Whole-Genome Genetic Risk in a Family Quartet Using a Major Allele Reference Sequence," *PloS Genetics*, Sept 15, 2011.

(2) "Personalis seeks edge with 'Enhanced' exome and genome sequencing, high quality annotations," J. Karow, *GenomeWeb*, March 6, 2013.

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.

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 the NeXT or NeXT Personal platforms, Personalis’ business opportunities, leadership, plans, or expectations, the presumed validity or enforceability of the company’s patents, the potential issuance of additional patents from the company’s pending or future patent applications, 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, the company’s registration statement on Form S-3 filed on December 30, 2020, and the company’s prospectus supplement filed on January 3, 2022, and include those listed under the caption “Risk Factors.” Personalis disclaims any obligation to update such forward-looking statements.

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