Personalis, ABRCC, and Criterium Announce Major Prospective Clinical Trial for Residual and Recurrent Disease Detection in Triple Negative Breast Cancer

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FREMONT, Calif.--(BUSINESS WIRE)--May 2, 2023--Personalis, Inc. (Nasdaq: PSNL) today announced it has partnered with the Academic Breast Cancer Consortium (ABRCC) and Criterium to carry out a prospective clinical trial, B-STRONGER-1 (Breast Cancer-Minimal Residual Disease Detection and Therapy Monitoring in Patients with Early Stage TNBC-Phase I), to evaluate the clinical performance of the NeXT Personal® test for detecting minimal residual disease (MRD) during and after treatment and recurrent cancer in patients with early-stage resectable triple-negative breast cancer (TNBC).

TNBC accounts for approximately 15%-20% of breast cancers diagnosed worldwide and is associated with worse outcomes compared to other breast cancer subtypes. Recurrence may be difficult to detect with other MRD assays, as TNBC in its earlier stages tends to 'shed' less circulating tumor DNA (ctDNA), a key marker for residual or recurrent cancer.

"The relatively high rate of recurrence in early stage TNBC patients makes detection of MRD after treatment important for assessing therapy response and providing opportunities for earlier intervention," said Richard Chen, MS, MD, Chief Medical Officer and Executive Vice President of R&D at Personalis. "However, in early-stage cancers like this, detection can be challenging because of lower ctDNA shedding rates. We specifically designed NeXT Personal to detect ctDNA with very high sensitivity. With the B-STRONGER-1 trial with ABRCC, Criterium and Dr. Chalasani, we hope to demonstrate that this high sensitivity enables earlier and more accurate detection of MRD in early stage TNBC patients."

Currently, a patient's likelihood of developing a recurrent tumor is largely determined through pathological assessment of tissue samples collected from both the site of the primary tumor and regional lymph nodes following treatment—a process broadly referred to as pathological complete response (pCR) testing.

"While a valuable tool in estimating the risk of recurrence, pCR doesn't help us to monitor for recurrence and response to treatment. More importantly, a large proportion of patients who do not have a pCR status have cancer recurrence. Currently we do not have good options in the clinic for detecting early recurrence. If we find it via imaging scans, it is too late, as this means the cancer has established a new 'home' already," explained the study's principal investigator, Pavani Chalasani, MD, Division Director for Hematology/Oncology, George Washington Cancer Center, George Washington University. "MRD testing has shown significant promise in recent years as a viable alternative, and it could become the new standard for assessing not only a patient's response to treatment, predicting their risk of recurrence, but also to detect early recurrence of disease. This early detection provides a window for the oncologist to potentially intervene and change treatment before the cancer can establish a new 'home'."

NeXT Personal leverages next-generation sequencing technology to detect ctDNA in the bloodstream and may enable detection of micrometastases that currently evade pCR detection. The assay is designed to deliver industry-leading MRD sensitivity down to 1 part-per-million, an approximately 10- to 100-fold improvement over other available technologies. This may enable earlier detection across a broader variety of cancers and stages.

The B-STRONGER-1 study will enroll approximately 900 patients at up to 30 US sites and will be carried out in two stages. In the first stage, samples will be collected from each patient for both pCR and MRD analyses, to assess whether MRD using NeXT Personal correlates with standard of care pCR measurements. The second stage will involve a five-year follow-up to deepen the evidence on performance and establish clinical utility of NeXT Personal in early stage resectable TNBC.

About Triple Negative Breast Cancer

Triple negative breast cancer (TNBC) is aggressive and strongly correlated with hereditary BRCA1/2 mutations as well as a higher prevalence in young African American women. Despite advances in systemic therapies, currently 25–30% of early stage patients develop metastatic disease within 3–5 years of diagnosis and subsequent overall survival ranges from 8–13 months.

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.

About Criterium and The Academic Breast Cancer Consortium (ABRCC)

Represented by Key Opinion Leaders (KOLs) and Top Investigators at the most prestigious institutions in the USA, ABRCC is one of 5 consortia formed and managed by Criterium to utilize translational science methodologies to streamline cancer research and development. Our Consortia model allows us to provide expertise and innovative solutions for the rapid design, implementation, management and completion of state of the art targeted and combination cancer trials. In addition to ABRCC, the Criterium oncology consortia include the Academic GI Cancer Consortium (AGICC), the Academic Thoracic Oncology Medical Investigators Consortium (ATOMIC), the Academic Myeloma Consortium (AMyC) and the Academic Urology Research Investigators Consortium (AURIC) comprising 65 member KOLs at 42 member Institutions. To learn more visit Oncology Consortia | Criterium CRO | Oncology Consortium.

Personalis Forward-Looking Statement

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 expected benefits of the B-STRONGER-1 clinical trial or Personalis’ collaboration with Criterium and the ABRCC, the clinical validity or performance of NeXT Personal in early stage TNBC, the capability of NeXT Personal to detect MRD or tumor recurrence in cancers like TNBC, 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 for Personalis:
Caroline Corner
investors@personalis.com
415-202-5678

Media Relations for Personalis:
Valerie Enes
pr@personalis.com
408-497-8568

Senior Project Manager for Criterium:
Ruth Stone
restone@criteriuminc.com

Media Contact for Criterium:
Claire Wynters
crwynters@criteriuminc.com
321-525-1285 (m)

Source: Personalis, Inc.