Personalis, National Cancer Center Hospital East, and Ono Collaborate to Better Predict Immunotherapy Response for Rectal Cancer

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Multicenter VOLTAGE-2 Phase II Trial Will Conduct Exploratory Biomarker Analysis Using Highly-Sensitive Genomic Platforms from Personalis

FREMONT, Calif. & KASHIWA, Japan & OSAKA, Japan--(BUSINESS WIRE)--May 16, 2023--Personalis, Inc. (Nasdaq: PSNL), National Cancer Center, and Ono Pharmaceutical Co., Ltd. today announced they have entered into a collaborative agreement to examine the efficacy and safety of *nivolumab*, an immune checkpoint inhibitor, for resectable rectal cancer with mismatch repair deficiency (dMMR). As part of the collaboration on the VOLTAGE-2 study, an exploratory analysis will be conducted to evaluate specific biomarkers such as minimal residual disease (MRD) status that may have prognostic or predictive value for patient care.

Under the agreement, National Cancer Center Hospital East (NCCHE) will recruit patients and conduct the clinical trial, Ono will provide *nivolumab,* and Personalis will perform MRD and biomarker testing. Biomarker research will be conducted throughout the study, including sample analysis from both tumor lesion tissue and plasma circulating tumor DNA (ctDNA). The Personalis NeXT Personal® platform will be used to correlate MRD status with standard of care imaging and drug response data by monitoring variances in ctDNA. Tissue samples will be analyzed by the Personalis ImmunoID NeXT® platform to capture tumor molecular profile and tumor microenvironment features to better understand immunotherapy responses.

“We deeply value the opportunity to work with NCCHE and Ono – respected oncology leaders worldwide – to demonstrate the clinical validity of our ultra-sensitive liquid biopsy MRD assay, NeXT Personal, in early-stage rectal cancer patients to better predict drug response and disease recurrence in subsequent interventional trials based on ctDNA status,” said Richard Chen, MS, MD, Executive Vice President, R&D and Chief Medical Officer at Personalis. “We believe that data from this study will be another step towards supporting the use of our highly sensitive MRD assay in rectal cancer and other cancer types.”

“In our VOLTAGE study, we will include patients with dMMR resectable rectal cancer, who are being treated with *nivolumab*. Using NeXT Personal, we would like to investigate if an MRD negative result can be the surrogate marker of clinical complete response,” said Hideaki Bando, MD, Assistant Chief, Department of Gastroenterology at NCCHE and Principal Investigator and Research Secretariat of the VOLTAGE-2 study. “We also would like to explore the association between immune microenvironment and efficacy of *nivolumab* using ImmunoID NeXT. These comprehensive assays may enable the selection of cases with high efficacies and will promote the non-operative management in dMMR rectal cancer.”

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.

Personalis 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 ImmunoID NeXT or NeXT Personal platforms, the expected benefits of the VOLTAGE-2 clinical trial or Personalis’ collaboration with NCCHE and Ono, the clinical validity or sensitivity of NeXT Personal in early stage rectal cancer or other cancer types, the capability of NeXT Personal to predict drug response or disease recurrence, 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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