NantHealth Announces FDA Marketing Authorization of Omics Core℠: The Nation's First Tumor-Normal Mutation Profiling of Overall Tumor Mutational Burden from Whole Exome Sequencing in Solid Tumors

November 12, 2019

- Landmark FDA clearance of whole exome sequencing in vitro diagnostic (IVD) test reporting overall tumor mutation burden (TMB) by sequencing 19,396 protein-coding genes (whole exome) targeting 39 million base pairs (39 Mb) of the human genome from patient tumor and matched normal sample (tumor-normal), for true determination of overall TMB, rather than the commonly-used formulaic extrapolation of TMB from gene panel sequencing.
- TMB, the measure of all acquired gene-coding mutations in a tumor genome, is an emerging biomarker predicting response to checkpoint therapy and identifies tumors that may benefit from immunotherapy.
- Omics Core additionally reports somatic mutations in 468 cancer-relevant genes accurate to 2% allele frequency providing a means to guide physician treatment decisions.

CULVER CITY, Calif.--(BUSINESS WIRE)-- NantHealth, Inc. (NASDAQ: NH), a next-generation, evidence-based, personalized healthcare company, today reported FDA authorization of Omics Core℠, the first whole exome tumor-normal in vitro diagnostic (IVD) that measures overall tumor mutational burden (TMB) in cancer tissue.

The Omics Core assay is the nation's first FDA authorized custom-targeted whole exome sequencing platform to report both overall tumor mutation burden in tumor specimens from 19,396 protein-coding genes (whole exome) and somatic alterations (point mutations, small insertions and deletions) in 468 cancer-relevant genes.

TMB is reported via two metrics:

1. Total number of somatic non-synonymous exonic variants within the 19,396 genes (whole exome) surveyed.
2. An estimate of mutation rate by counting all somatic, synonymous and non-synonymous variants detected in gene coding regions and dividing by the approximate size of the whole exome.

"*Tumor mutation burden (TMB) is now recognized as a key biomarker across multiple tumor types. Studies have shown that immunotherapy treated patients with high TMB had better outcomes compared to those with low TMB. Since the potential for TMB as a precision medicine tool is so high, it is imperative that the most accurate and comprehensive method of analysis be applied to enable physicians to determine which tumors could benefit from checkpoint inhibitors and immunotherapy,*" said Patrick Soon-Shiong, MD, Chairman & CEO NantHealth. "*I am so proud of the scientific, regulatory and bioinformatics teams who have spent almost a decade to perfect this important test that measures the absolute number of mutations occurring in 19,396 protein-coding genes (whole exome) targeting 39 million base pairs (39 Mb) of the human genome from both a*

tumor and patient-matched normal control sample (tumor-normal). We believe that this comprehensive diagnostic will provide greater accuracy than the widely-used formulaic extrapolation of TMB from a limited gene panel sequence ," said Soon-Shiong.

"*Omics Core is the first whole exome test for TMB authorized by the FDA, and as such, marks a watershed moment in oncology. Clinicians can now directly measure the mutations in a patient's tumor specimen accurately via tumor-normal sequencing and have confidence that the results they receive are fully validated to help support better therapeutic decisions. Also, the breadth of a whole exome means that many more neoepitopes and novel targets may be identified to support vaccine development, novel drug development, and therapies for previously undruggable targets*," said Sandeep Bobby Reddy, MD - Chief Medical Officer, NantHealth

"Multiple groups, including our own presentation at ASCO in 2018, have shown the importance of performing whole exome sequencing to measure the comprehensive TMB. We calculated a three-fold overestimation of TMB when extrapolating from panel-based methods, potentially leading physicians to over-prescribe checkpoint inhibitors for patients that are unlikely to respond. Given the high cost and the possibility of adverse events with these therapies, it is critical we identify the most appropriate population as accurately as possible," said Steve Benz, PhD - President, Genomics, ImmunityBio.

"*Determining the tumor mutational burden from whole exome sequencing is the first step in defining neoepitopes. These unique tumor mutations are recognized by T cells and elicit an immunological anti-tumor response. Patients with high TMB typically have more neoepitopes that attract cancer killing T cells to the tumor microenvironment. Identifying neoepitopes from whole exome TMB enables the development of neoepitope-targeted vaccines for the >95% of protein-encoding genes not covered by limited gene panel tests and the >99% of genes not directly targeted by drugs today. The clearance of Omics Core based upon its analytical performance and validity in reporting TMB establishes a new chapter in the era of precision cancer immunotherapy,"* said Shahrooz Rabizadeh, PhD - Chief Scientific Officer, ImmunityBio.

About Omics Core

The Omics Core assay is a qualitative in vitro diagnostic test that uses targeted next generation sequencing of formalin-fixed paraffin-embedded tumor tissue matched with normal specimens from patients with solid malignant neoplasms to detect tumor gene alterations in a broad multi gene panel. The test is intended to provide information on somatic mutations (point mutations and small insertions and deletions) and tumor mutational burden (TMB) for use by qualified health care professionals in accordance with professional guidelines, and is not conclusive or prescriptive for labeled use of any specific therapeutic product. Omics Core is a single-site assay performed at NantHealth, Inc. The Omics Core assay is protected by US Patents 9,652,587; 9,646,134; 9,824,181; 10,249,384; 9,721,062; 10,242,155; 10,268,800.

About NantHealth, Inc.

NantHealth, a member of the NantWorks ecosystem of companies, provides leading solutions across the continuum of care for physicians, payors, patients, and biopharmaceutical organizations. NantHealth enables the use of cutting-edge data and technology toward the goals of empowering clinical decision support and improving patient outcomes. NantHealth's comprehensive product portfolio combines the latest technology in payor/provider platforms that exchange information in near-real time (NaviNet and Eviti), connected care solutions that deliver medical device interoperability (DCX device connectivity platform and VCX patient vitals software) and molecular profiling services that include comprehensive DNA & RNA tumor-normal whole genome profiling with pharmacogenomics analysis (GPS Cancer®; laboratory developed test) and tumor-normal in

vitro diagnostic (Omics Core℠; In Vitro Diagnostic) profiling to report somatic alterations in 468 genes and sequencing of 19,396 protein-coding genes to determine overall tumor mutation burden. For more information, please visit Nanthealth.com or follow us on Twitter, Facebook and LinkedIn.

This news release contains certain statements of a forward-looking nature relating to future events or future business performance. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Risks and uncertainties include, but are not limited to: our ability to successfully integrate a complex learning system to address a wide range of healthcare issues; our ability to successfully amass the requisite data to achieve maximum network effects; appropriately allocating financial and human resources across a broad array of product and service offerings; raising additional capital as necessary to fund our operations; achieving significant commercial market acceptance for our sequencing and molecular analysis solutions; establish relationships with, key thought leaders or payers' key decision makers in order to establish our sequencing and molecular analysis solutions as a standard of care for patients with cancer; our ability to grow the market for our systems infrastructure, and applications; successfully enhancing our systems infrastructure and applications to achieve market acceptance and keep pace with technological developments; customer concentration; competition; security breaches; bandwidth limitations; our ability to continue our relationship with NantOmics; our ability to obtain regulatory approvals; dependence upon senior management; the need to comply with and meet applicable laws and regulations; unexpected adverse events; clinical adoption and market acceptance of our sequencing and molecular analysis solutions; and anticipated cost savings. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our reports filed with the Securities and Exchange Commission.

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