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Lucence Launches US Validation Study for LiquidHALLMARK® Liquid Biopsy Test for Biomarker Detection in Lung Cancer

PALO ALTO, CA

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Precision oncology company Lucence is currently conducting the first US validation study of its technology, examining the use of the company's amplicon-based LiquidHALLMARK liquid biopsy assay versus tissue biopsy in detecting guideline-recommended biomarkers in lung cancer.

LIQUIK, Liquid Biopsy for Detection of Actionable Genomic Biomarkers in Patients With Advanced Non-Small Cell Lung Cancer, aims to better understand the concordance of LiquidHALLMARK with conventional tissue-based profiling. The prospective study will enroll 200 treatment-naive newly diagnosed metastatic non-squamous cell lung cancer (NSCLC) patients. Its primary endpoint is to compare LiquidHALLMARK with tissue next-generation sequencing (NGS) for mutation profile results in NSCLC patients who have at least one of nine clinically relevant genes— EGFR, ALK, RET, ROS1, NTRK fusions, MET, BRAF, ERBB2 and KRAS—detected by tissue biopsy. LIQUIK has enrolled its first patient and will continue enrollment across 7 study sites nationwide.

"The launch of our first prospective multicenter study in the United States brings us one step closer to advancing precision cancer care for the benefit of patients everywhere," said Dr. Min-Han Tan, founding CEO of Lucence. "Building evidence to support the clinical utility and sensitivity of our test will enable us to make LiquidHALLMARK's high resolution, target-rich insights more widely available to patients across the country."

Liquid biopsy holds promise for a range of applications across cancer including non-invasive screening, biomarker detection, treatment monitoring, and testing for minimal residual disease. For non-small cell lung cancer, liquid biopsy is a NCCN Guidelines-recommended option for testing in cases where a tissue biopsy is not feasible either due to the patient being medically unfit for an invasive procedure or there is insufficient material for molecular analysis.

LiquidHALLMARK is a comprehensive, amplicon-based NGS assay for ultrasensitive biomarker detection. Powered by AmpliMark™, a proprietary sequencing technology, LiquidHALLMARK examines plasma circulating tumor DNA mutations in 80 genes, including fusions in 10 genes. LiquidHALLMARK provides >99% sensitivity at a detection limit of 0.1% variant allele frequency, and targets single nucleotide variants (including cis-trans), insertions and deletions, copy

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number variations, microsatellite instability, fusions, and viruses. LiquidHALLMARK targets have been identified in 15 cancers.

AmpliMark is the foundational technology in Lucence's liquid biopsy tests. AmpliMark uses a unique molecular barcode and error-correction technology designed to improve liquid biopsy test sensitivity for single nucleotide variants and fusion genes.

Late last year Lucence's Palo Alto laboratory received certification from the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. LiquidHALLMARK is currently available to US oncologists as a laboratory developed test.