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Amplicon-Based Liquid Biopsy Platform Complements Tissue Genotyping in Detection of Guideline-Recommended Biomarkers in Metastatic NSCLC

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Introduction: Liquid biopsy offers non-invasive testing of NCCN guideline recommended biomarkers (EGFR, ALK, ROS1, RET, BRAF, MET, KRAS, ERBB2, and NTRK1/2/3) for non-Small cell Lung cancer (NSCLC) where tissue-genotyping may not be feasible. LiquidHALLMARK is an amplicon-based next-generation sequencing (NGS) liquid biopsy, intended to detect alterations in 80 genes. Sensitivity can vary between variant types, with Single nucleotide variation (SNV) detection having higher concordance than large fusion rearrangements.

Methods: LIQUIK-01 (LIQUId Biopsy for Detection of Actionable Genomic BiomarKers in Patients with Advanced Non-small Cell Lung Cancer) is a prospective study comparing different liquid biopsies, including LiquidHALLMARK, with conventional tissue-genotyping. 200 treatment-naïve metastatic non-squamous NSCLC subjects will be enrolled from 11 USA and Singapore sites. The 1st interim analysis on 45 patients was published at the IASLC2022 North America Conference on Lung Cancer. This 2nd interim analysis conducted at 01 July 2022 cut-off includes additional recruitment and comparisons. Primary endpoints include non-inferiority of LiquidHALLMARK (Lucence,CA; Singapore) compared with tissue biopsy in 9 guideline recommended biomarkers (G9) detection; and a comparison of LiquidHALLMARK with Guardant360 (Guardant,CA), a hybrid-capture-based NGS test, for patients with G9 biomarkers detected by tissue-genotyping.

Results: For the 60 patients enrolled by the cut-off date, at least one G9 biomarker was identified in 33 patients (55%) by tissue-genotyping versus 29 patients (48.3%) by LiquidHALLMARK. 34 G9 biomarkers were identified in the 33 tissue-positive patients. At least 1 G9 biomarker was detected in 24/33 patients (72.7%) by LiquidHALLMARK and 21/33 patients (63.6%) by Guardant360. One tissue-positive patient sample had 2 G9 biomarkers identified by LiquidHALLMARK. Comparing variant classes detected, LiquidHALLMARK identified 20 SNVs/insertion-deletion mutations(Indels), 4 rearrangements, 1 amplification, while Guardant360 identified 18 SNVs/Indels, 2 rearrangements, 1 amplification. For the 27 patients with tissue-negative or insufficient tissue, LiquidHALLMARK detected G9 biomarkers in 5 patients (18.5%). Concordance for G9 biomarkers between LiquidHALLMARK and tissue-genotyping was 94.5-100%.

Conclusion: Liquid biopsy is valuable as a complementary tool in guideline-recommended biomarker detection. More G9 biomarkers were identified by LiquidHALLMARK in comparison to Guardant360 thus far, supporting further recruitment and investigations.