Validation Data On A Novel Prognostic Test Developed By GRAIL In Stage I Lung Cancer Presented At North America Conference On Lung Cancer

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Validation Results Using a Plasma-based Targeted Methylation Assay Demonstrate Potential to Identify High-Risk Patients who Might Benefit From Additional Treatment

MENLO PARK, Calif. CAMBRIDGE, UK, and SEOUL, South Korea, Dec. 6, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, highlighted the presentation of analytical and clinical validation data on a novel prognostic test in early-stage lung cancer, generated through collaboration with the Samsung Medical Centre and AstraZeneca (LSE/STO/Nasdaq: AZN). The results of the studies demonstrate sensitive and specific detection of circulating tumor DNA (ctDNA) for Lung Adenocarcinoma (LUAD) at a clinically meaningful threshold for disease prognostication. This is a novel tissue-free diagnostic that has the potential to identify high-risk patients prior to surgery and/or treatment. The findings were presented in poster sessions at the North America Conference on Lung Cancer 2023 in Chicago, held Dec. 1-3, 2023.

“These results are an important step in establishing oncology capabilities for GRAIL’s Methylation Platform for important cancer-specific applications beyond early cancer detection,” said Jeffrey Venstrom, MD, Chief Medical Officer at GRAIL. “These studies demonstrate that a new tissue-free methylated ctDNA assessment in Stage I lung cancer can potentially identify patients at higher risk for recurrence.”

The clinical validation studies analyzed pre-surgical plasma samples from 602 patients with EGFR/ALK wild-type clinical Stage I NSCLC (staging determined by TNMv8). A GRAIL assay was used to measure ctDNA detection with a prespecified threshold in a prospectively defined retrospective study. The presence of ctDNA correlated with an inferior two-year recurrence-free survival (HR 3.8 [95%CI 2.3–6.4], P<0.001 comparing ctDNA+ versus ctDNA-). ctDNA positivity in clinical stage I LUAD was associated with higher rates of mediastinal nodal upstaging at resection, PD-L1 positivity, and grade 3 histology.

In addition, analytical studies demonstrate analytical specificity of 96.9% (as determined in healthy donors), 100% accuracy to detect signal at low ctDNA input (2ng) and a robust LoD95 of 44 ppm tumor methylated fraction (TMeF: a measure of ctDNA abundance).

In 2022, GRAIL announced a broad strategic collaboration with AstraZeneca to develop and commercialize companion diagnostic (CDx) assays for use with AstraZeneca’s therapies.

In January 2023, GRAIL announced the availability of its state-of-the-art research use only (RUO) methylation solution which is being leveraged by pharmaceutical companies for custom oncology applications.

About GRAIL
GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate from Illumina Inc. under the terms of the Interim Measures Order of the European Commission.

For more information, please visit grail.com.

Laboratory/Test Information
GRAIL’s clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. GRAIL’s clinical laboratory is regulated under CLIA to perform high-complexity testing. The RUO test was developed, and its performance characteristics were determined by GRAIL. The RUO test is for research use only, not for diagnostic purposes. GRAIL’s current product offerings have not been cleared or approved by the U.S. Food and Drug Administration.

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