GRAIL Announces Novel Risk Classification Test to be Used in Lung Cancer Study

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MENLO PARK, Calif. and CAMBRIDGE, UK, Mar. 18, 2024 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, announced today that participants from Japan, via a collaboration with AstraZeneca (LSE/STO/Nasdaq:AZN), will have their samples tested using GRAIL's novel risk classification test on its Methylation Platform. This assay has been validated for recurrence risk classification in newly diagnosed Stage I lung adenocarcinoma.

GRAIL's Methylation Platform enables tissue-free, blood-based cancer detection that can be customized for a suite of precision applications across hematological and solid tumors, including risk stratification, molecular subtyping, and molecular response. This study with AstraZeneca aims to demonstrate the test's capability to deliver results within 10 days without the need for tumor tissue, supporting use in future global pharmaceutical clinical trials.

"The development of this risk classification test as part of GRAIL's clinical oncology portfolio is a significant milestone in our ongoing commitment to support patient care with novel, non-invasive tests for early detection and beyond," said Jeffrey Venstrom, MD, Chief Medical Officer at GRAIL. "GRAIL's tissue-free, blood-only methodology is designed to aid in clinical trial selection with potential for customizable diagnostic approaches that can enable precision oncology."

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 December 2023, GRAIL announced the analytical and clinical validation of a novel prognostic test in Stage I lung adenocarcinoma.

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. GRAIL's current product offerings have not been cleared or approved by the U.S. Food and Drug Administration.

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