GRAIL Announces First Patient Tested With Blood-Based Assay in Global Phase 3 Adjuvant Lung Cancer Study

November 18, 2024

MENLO PARK, Calif., Nov. 18, 2024 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced that the first patient has been tested for eligibility with the investigational GRAIL Non-Small Cell Lung Cancer (NSCLC) ctDNA Assay in the global TROPION-Lung12 Phase 3 study evaluating adjuvant treatment regimens in patients with Stage I adenocarcinoma NSCLC. The study is sponsored by AstraZeneca (LSE/STO/Nasdaq:AZN) in collaboration with Daiichi Sankyo (TSE: 4568).

The study, which is being conducted under an FDA-approved Investigational Device Exemption application, held by GRAIL, leverages GRAIL's targeted methylation platform to detect ctDNA. With GRAIL's blood-only approach, tissue analysis and bespoke panel development are not required, enabling simple integration into pharmaceutical clinical trial workflows. In TROPION-Lung12, patients will be screened with the GRAIL assay prior to surgery to inform eligibility for post-surgery randomization to an adjuvant treatment regimen (NCT06564844). Assay performance was previously reported in the *Journal of Thoracic Oncology* and presented at the 2023 North America Conference on Lung Cancer.

"We're excited to continue our strategic collaboration with AstraZeneca with the use of our novel assay in the TROPION-Lung12 study. We hope this study will further demonstrate the potential of GRAIL's Methylation Platform to enhance patient selection for cancer treatment," said Harpal Kumar, President, International Business & Biopharma, at GRAIL. "GRAIL's ctDNA detection approach, which does not require tumor tissue, has the potential to offer oncologists a rapid, accessible method to help refine patients' diagnostic and prognostic profiles for better guided cancer therapy. This is among the first times a ctDNA assay has been used in a clinical trial of early-stage lung cancer patients to identify those most likely to benefit from further treatment. As such, we hope this approach could provide substantial additional benefit for patients diagnosed with Stage 1 lung cancer."

"In TROPION-Lung12, screening for ctDNA is intended to identify the patients at an increased risk of disease recurrence after surgery and thus most likely to benefit from adjuvant therapy," said Cristian Massacesi, MD, Chief Medical Officer and Oncology Chief Development Officer, AstraZeneca. "The novel strategy we are deploying in this trial illustrates our commitment to both detect cancer earlier and use those early insights to enable more personalized treatment decisions for the benefit of patients."

In 2022, GRAIL announced a broad strategic collaboration with AstraZeneca to develop and commercialize companion diagnostic (CDx) assays for use with AstraZeneca's therapies. GRAIL is committed to leveraging its blood-based methylation testing for patient care by developing fit-for-purpose diagnostics to enable precision oncology strategies with biopharma partners.

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 using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art machine learning, software, and automation to detect and identify multiple deadly cancer types in earlier stages. GRAIL's targeted methylation-based platform can support the continuum of care for screening and precision oncology, including multi-cancer early detection in symptomatic patients, risk stratification, minimal residual disease detection, biomarker subtyping, treatment and recurrence monitoring. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom.

For more information, 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.

Forward Looking Statements
This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would," or "will," the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include statements about benefits for patients with lung cancer, expectations and projections of future tests or products, technology, clinical studies, regulatory compliance, future investment and strategy and anticipated trends in our business.

These statements are only predictions based on GRAIL's current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors discussed under the section entitled "Risk Factors" in GRAIL's most recent Quarterly Report on Form 10-Q filed with the SEC. Moreover, GRAIL operates in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for GRAIL's management to predict all risks, nor can they assess the impact of all factors on GRAIL's business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements GRAIL may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are

difficult to predict and many of which are outside of GRAIL's control. Although GRAIL believes the expectations and projections expressed or implied by the forward-looking statements are reasonable, GRAIL cannot guarantee future results, level of activity, performance, or achievements. GRAIL's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, GRAIL undertakes no obligation to update any of these forward-looking statements after the date of this press release to conform its prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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