GRAIL Presents Initial Results From REFLECTION Real-World Evidence Study of Galleri® Multi-Cancer Early Detection (MCED) Test at the Early Detection of Cancer Conference

October 23, 2024

Study Participants from Veteran Affairs Sites Include a Diverse Population With Toxic Exposure

MENLO PARK, Calif., Oct. 23, 2024 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced early results from the REFLECTION study, which aims to understand the real-world experience of the Galleri® multi-cancer early detection (MCED) test in routine clinical settings. The Galleri test is recommended for adults with an elevated risk for cancer, such as those age 50 or older. In this study, a diverse population of veterans from U.S. Department of Veterans Affairs (VA) sites with toxic exposure but with no symptoms suggestive of cancer were included in study enrollment. Initial results showed that among study participants, the veteran cohort had a cancer signal detection rate consistent with other populations that have received the MCED test. The findings were presented during a presentation at the 2024 Early Detection of Cancer Conference (EDCC).

Overall, the cancer signal detection rate in this veteran cohort was 1.30% (37/2854 participants; 95% CI: 0.94% - 1.78%), which is consistent with other populations that have received the MCED test (0.88%[1] and 0.95%[2]). Among the 37 participants with a Cancer Signal Detected (CSD) at the time of analysis, 28 completed 180 days of follow-up, and of these, 12 cancer diagnoses were confirmed. More than half of the cases were identified at early stages (I-III) and the most common cancer signal of origin prediction was lung cancer (7). A positive predictive value (PPV), meaning that the test accurately detects a signal for cancer in someone that has cancer, was 42.9%, which is consistent with PPVs from previous Galleri testing datasets.[1,3] Additional cancers could be diagnosed during the remainder of the one-year follow-up period.

"While today doctors screen individually for five specific cancers, nearly 70% of cancers have no recommended screening tests. With 50,000 veterans diagnosed with cancer every year, these initial findings from REFLECTION showing a consistent cancer signal detection rate among the veteran cohort suggest that when added to recommended screenings, MCED tests like Galleri may address an unmet medical need," said Charles Atwood, M.D., pulmonologist and lead researcher on the REFLECTION study at VA Pittsburgh. "We look forward to longer-term data that will provide veteran-reported experience with MCED testing and cancer outcomes that may provide additional insights for veterans with service-related toxic exposures."

The REFLECTION study (NCT05205967) is a multi-center, prospective, non-interventional, cohort study designed to understand the real-world experience of Galleri in clinical settings. This initial analysis included data from seven VA sites with 180 days of post-test follow-up. A total of 2,924 veterans were enrolled in the study at the time of the analysis and 2,854 are analyzable in these initial study data. Within the veteran cohort with data, 70% of participants had been exposed to one or more toxic environmental or occupational hazards during their service, including open burn pits/airborne hazards, Gulf War-related exposures, Agent Orange, radiation and others. The study included recruitment of veterans aged ≥22 years. The mean age of the cohort was 60 years old and the cohort was 79% male.

"With many veterans at elevated risk of developing cancer, the initial results from the REFLECTION study provide important insights into the impact of MCED testing to help transform early cancer detection in a real-world setting," said Josh Ofman, MD, MSHS, President at GRAIL. "We're honored to be working with the VA, the largest national integrated health system in the U.S., to evaluate how Galleri can screen for many of the deadliest cancers before they become symptomatic, when there may be more treatment options."

About the REFLECTION Study
REFLECTION is a multi-center, prospective, non-interventional, cohort study that will enroll approximately 17,000 individuals who have opted to be screened with the Galleri, multi-cancer early detection (MCED) test in routine clinical settings. The purpose of the study is to understand the real-world experience of Galleri in clinical settings. Patients who have been prescribed the Galleri test as part of medical care by their healthcare provider will have the opportunity to consent for participation into this data collection study and will be actively followed for 12 months from the time of enrollment through data capture from electronic health records and periodic self-report questionnaires.

About GRAIL, Inc.
GRAIL, Inc. 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.

About Galleri®
The Galleri multi-cancer early detection test is a proactive tool in finding cancer early. With a simple blood draw, the Galleri test can identify DNA shed by cancer cells (unique "fingerprints") to help screen for some of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, liver, and others.* The Galleri test can be used to screen for cancer before a person becomes symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test can indicate the origin of the cancer, giving healthcare providers a roadmap

of where to explore further. The Galleri test requires a prescription from a licensed healthcare provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. It is recommended for people over the age of 50, or those with an elevated risk for cancer due to genetics, family history, environmental exposure, or other risk factors.

For more information about Galleri, visit galleri.com

Laboratory/Test Information
The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the U.S. Food and Drug Administration. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

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 expectations and projections of test performance , clinical study results, regulatory compliance, potential market opportunity, anticipated growth strategies, and anticipated trends in our business.

These statements are only predictions based on our 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 the Quarterly Report on Form 10-Q for the period ended June 30, 2024 and in GRAIL's other filings with the U.S. Securities and Exchange Commission (the "SEC") . Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our 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 we 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 our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this press release to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events. Footnotes:

1. Schrag D et al. *Lancet*. 2023;402(10409):1251-1260.
2. Westgate C et al. Poster presented at American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023, Chicago, IL.
3. Klein et al. *Ann Oncol*. 2021;32(9):1167-1177.

View original content to download multimedia:https://www.prnewswire.com/news-releases/grail-presents-initial-results-from-reflection-real-world-evidence-study-of-galleri-multi-cancer-early-detection-mced-test-at-the-early-detection-of-cancer-conference-302285125.html

SOURCE GRAIL, Inc.

CONTACTS: Corporate Communications, Kristen Davis, Trish Rowland, pr@grail.com; Investor Relations, Alex Dobbin, Alexis Tosti, ir@grail.com