GRAIL Advances the Galleri® Registrational Clinical Trial Program

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GRAIL Completes Enrollment of More Than 35,000 Participants in the PATHFINDER 2 Study; Results From the First 25,000 Participants Expected in the Second Half of 2025

GRAIL Completes Final Study Visits for the NHS-Galleri Trial; Final Results Expected in 2026

MENLO PARK, Calif., July 15, 2024 /PRNewswire/ -- GRAIL, Inc. (NASDAQ: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today provided an update on the PATHFINDER 2 and NHS-Galleri registrational clinical trials evaluating the Galleri® multi-cancer early detection (MCED) test. GRAIL has completed the PATHFINDER 2 study's planned enrollment of more than 35,000 participants who are eligible for guideline-recommended cancer screening at more than 30 healthcare institutions in North America. In addition, GRAIL has completed the third and final round of study visits for the NHS-Galleri trial, which enrolled more than 140,000 participants.

"The PATHFINDER 2 and NHS-Galleri studies will significantly expand our existing clinical validation and performance evidence for the Galleri test. By supplementing our robust clinical evidence program with more than 35,000 participants in the U.S. for PATHFINDER 2 and over 140,000 participants in England for NHS-Galleri, we will continue our generation of additional performance, safety, and clinical utility data," said Bob Ragusa, Chief Executive Officer at GRAIL. "Both studies were designed to enroll a diverse participant population, representative of socio-economic, ethnicity, gender and age differences, and we are proud of the diversity of the study populations. The data from these studies, as well as supplemental data from our other clinical studies, will support our premarket approval application submission for Galleri to the FDA, which is currently in process with a modular submission under a Breakthrough Device Designation from the FDA. We look forward to seeing results from the first 25,000 individuals enrolled in the PATHFINDER 2 study in the second half of 2025 and final results from the NHS-Galleri trial in 2026."

About the PATHFINDER 2 Study (NCT05155605)
PATHFINDER 2 is a prospective, multi-center, interventional study evaluating the safety and performance of Galleri in a population of individuals aged 50 years and older who are eligible for guideline-recommended cancer screening in the United States. PATHFINDER 2 is being conducted pursuant to an FDA-approved investigational device exemption (IDE) application and began enrolling in December 2021. The primary objectives of the study are 1) to evaluate the safety and effectiveness of GRAIL's MCED test based on the number and type of diagnostic evaluations performed in participants who receive a cancer signal detected test result, and 2) to evaluate the performance of GRAIL's MCED test across various measures, including positive predictive value (PPV), negative predictive value (NPV), sensitivity, specificity, and cancer signal origin (CSO) prediction accuracy. Participants who receive a cancer signal detected result undergo additional diagnostic testing based on the predicted CSO to determine if a cancer is present. Secondary objectives include utilization of guideline-recommended cancer screening procedures after use of the MCED test, and participant reported outcomes (PRO) over several time points, including an assessment of participants' anxiety and satisfaction with the MCED test. Timepoints for collection will include baseline measurement prior to testing, post-results, and post-diagnostic resolution for positive test results.

The PATHFINDER 2 study is being conducted with leading healthcare institutions across the United States, including Cleveland Clinic, Duke University Health System, Flushing Hospital Medical Center, Henry Ford Health System, Hoag, Inova, Jamaica Hospital Medical Center, Kelsey-Seybold Clinic, Mayo Clinic, Morehouse School of Medicine, Ochsner Health, Oregon Health & Science University, Sarah Cannon, Sutter Health, University of Oklahoma, University of Pittsburgh, Virginia Commonwealth University, Weill Cornell Medicine, and others.

About the NHS-Galleri Trial (NCT05611632)
In 2020, NHS England selected GRAIL to assist with the United Kingdom's ambitions for early cancer detection and to assess Galleri for potential population screening on a national scale. In 2021, we initiated the NHS-Galleri trial, a fully enrolled prospective randomized controlled clinical utility trial of over 140,000 participants between the ages of 50 and 77 at the time of enrollment, to evaluate the implementation of Galleri alongside the existing NHS standard of care screenings. The primary objective of the trial is to assess whether implementation of Galleri can reduce the incidence of late-stage cancers through early cancer detection. The trial aimed to enroll a representative population sample to promote health equity and was fully enrolled in just over 10 months.

The trial is designed for participants to provide three blood draws over a two-year period, with the first draw taken at enrollment. As a randomized controlled trial, half of the trial participants have received the Galleri test, and half have had their blood sample stored for future analysis. Any participant in the interventional arm with a cancer signal detected result has been referred for further diagnostic workup within the NHS. All other participants and their physicians remain blinded as to which arm of the study they are in. The NHS-Galleri trial design was published in Cancers in 2022.

Collaborators include Queen Mary University of London, King's College London Cancer Prevention Trials Unit, and NHS England.

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

* Sensitivity in study participants with – Pancreas cancer: 83.7% overall (61.9% stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). Esophagus cancer 85.0% overall (12.5% stage I, 64.7% stage II, 94.7% stage III, 100% stage IV). Ovary cancer: 83.1% overall (50.0% stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV). Liver/bile duct cancer: 93.5% overall (100% stage I, 70.0% stage II, 100% stage III, 100% stage IV).

Important Galleri Safety Information
The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of Cancer Signal Not Detected does not rule out cancer. A test result of Cancer Signal Detected requires confirmatory diagnostic evaluation by medically established procedures (e.g., imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

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 generation of clinical data, use of data in our future regulatory filings, timing of data readouts, or other statements regarding our clinical studies and regulatory compliance, and statements relating to our future performance, future tests or products, technology, potential market opportunity, anticipated growth strategies, and anticipated trends in our business and our spin-off from Illumina.

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 our Registration Statement on Form 10 filed on June 3, 2024 (the "Form 10"), as may be further amended. 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, achievement 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.

This press release shall not constitute an offer of any securities for sale, nor shall there be any offer, sale or distribution of securities in any jurisdiction in which such offer, sale or distribution would be unlawful prior to appropriate registration or qualification under the securities laws of such jurisdiction.

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