GRAIL Announces Positive Top-Line Results From The Galleri® PATHFINDER 2 Registrational Study

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Cancer Detection and Positive Predictive Value Substantially Higher Than the Previously Published PATHFINDER Study

MENLO PARK, Calif., June 18, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced positive top-line performance and safety results from the pre-specified analysis of the first 25,578 participants in GRAIL's registrational PATHFINDER 2 study. PATHFINDER 2 was initiated in 2021 to evaluate the safety and performance of the Galleri® multi-cancer early detection (MCED) test when added to standard of care single cancer screening in 35,878 adults over 50 years of age with no clinical suspicion of cancer.

In the previously published PATHFINDER study, adding Galleri to standard of care cancer screening more than doubled the overall number of cancers detected by screening. In PATHFINDER 2, adding Galleri to standard of care screening demonstrated substantially greater additional cancer detection than in PATHFINDER.

In PATHFINDER, Galleri demonstrated a positive predictive value (PPV), or likelihood that a positive Galleri test was confirmed to be cancer, of 43%; specificity of 99.5%; and 88% cancer signal origin (CSO) accuracy. Data from evaluable PATHFINDER 2 participants with 12 months of follow-up showed a substantially higher PPV than that observed in the PATHFINDER study. CSO accuracy and specificity were consistent with that observed in the PATHFINDER study.

There were no serious safety concerns reported in PATHFINDER 2.

"We are delighted to see very encouraging performance of the Galleri MCED test as a cancer screening tool in broad intended use populations of asymptomatic adults over 50 years of age in both the PATHFINDER 2 study and the NHS-Galleri trial's prevalent screening round," said Josh Ofman, MD, MSHS, President at GRAIL. "We would like to extend our sincere gratitude to all of the participants and investigators in both of these pivotal studies, who are collectively helping to realize the potential of this groundbreaking technology for population-scale multi-cancer early detection and move the field forward. We look forward to sharing the detailed PATHFINDER 2 data at a medical congress later this year."

PATHFINDER 2 study results will be submitted to the U.S. Food and Drug Administration (FDA) as part of the Galleri premarket approval application (PMA), along with data from the prevalent screening round of the NHS-Galleri trial. In addition, GRAIL will submit to the FDA bridging analyses to compare performance of the version of Galleri used in the PATHFINDER 2 study and the NHS-Galleri trial to the updated version that GRAIL plans to submit to the FDA for premarket approval. The PMA for Galleri is currently in process with a modular submission under a Breakthrough Device Designation from the FDA. GRAIL expects to complete the PMA modular submission in the first half of 2026.

Detailed results from the PATHFINDER 2 study will be submitted for presentation at a leading international oncology meeting before the end of the year.

About the PATHFINDER 2 Study (NCT05155605)
PATHFINDER 2 is a prospective, multi-center, interventional study evaluating the safety and performance of Galleri in approximately 35,000 individuals aged 50 years and older who are eligible for guideline-recommended cancer screening in the United States. The primary objectives of the study are 1) to evaluate the safety and effectiveness of the Galleri 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 the Galleri MCED test across various measures, including PPV, negative predictive value (NPV), sensitivity, specificity, and 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.

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.

About Galleri®
The Galleri multi-cancer early detection test is a proactive tool to screen for cancer. With a simple blood draw, the Galleri test can identify DNA shed by cancer cells, which can act as a unique "fingerprint" of cancer, 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. The Galleri test is recommended for adults with an elevated risk for cancer, such as those aged 50 or older.

For more information, visit galleri.com.

Important Galleri Safety Information
The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those age 50 or older. The test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. The Galleri test is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of the test 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 No Cancer Signal 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 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, include the benefits and use of the Galleri test, the potential of the Galleri MCED test, upcoming events and presentations, the timeline for submission of PATHFINDER 2 study results and a bridging analyses to the FDA, and the timeline for completion of the PMA modular submission.

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 and numerous associated risks discussed under the section entitled "Risk Factors" in our Annual Report on Form 10-Q for the period ended March 31, 2025 and our Form 10-K for the period ended December 31, 2024 (the "Form 10-K"). 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.

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