GRAIL PATHFINDER 2 Results Show Galleri ® Multi-Cancer Early Detection Blood Test Increased Cancer Detection More Than Seven-Fold When Added to USPSTF A and B Recommended Screenings

October 17, 2025

More Than Half of Cancers Detected by Galleri Were Early Stage

Approximately Three-Quarters of Galleri-Detected Cancers Do Not Have Recommended Screenings

PATHFINDER 2 is the Largest U.S. Multi-Cancer Early Detection (MCED) Interventional Study in the Cancer Screening Population

MENLO PARK, Calif., Oct. 17, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced that positive performance and safety results from its registrational PATHFINDER 2 study are being presented at the European Society for Medical Oncology (ESMO) Congress 2025[1].

PATHFINDER 2 evaluated the safety and performance of the Galleri® multi-cancer early detection (MCED) test when used alongside standard-of-care cancer screenings. The largest interventional study of an MCED test in the United States to date, the prospective PATHFINDER 2 study includes 35,878 enrolled participants across the United States and Canada in a broad, intended-use population of adults aged 50 and older with no clinical suspicion of cancer. Results were presented from a pre-specified analysis of the first 25,578 participants with at least 12 months of follow-up as of Dec. 31, 2024. Of these, 23,161 were analyzable for performance and 25,114 were analyzable for safety.

"Cancer is the second leading cause of death worldwide as most deadly cancers are found too late. Adding Galleri to recommended screening for breast, cervical, colorectal, and lung cancers in PATHFINDER 2 yielded a more than seven-fold increase in the cancer detection rate, and more than half of the Galleri detected new cancers were found in early stages, when cancers are more treatable and potentially even curable. Galleri's ability to accurately predict where in the body the cancer signal comes from also helps to guide a more efficient diagnostic workup," said Josh Ofman, MD, MSHS, President at GRAIL. "These results are extremely compelling as approximately three-quarters of the Galleri-detected cancers do not have recommended screening tests today. Galleri is the only MCED test available that has been validated in an interventional trial in the screening population and could transform how we deliver cancer screening at a population level."

Finding More Cancers, Earlier By Adding the Galleri Test
Data from the performance analyzable cohort of 23,161 participants with 12 months of follow-up found that adding Galleri to recommended screenings for breast, cervical, colorectal, and lung cancers (USPSTF A and B recommendations) led to a more than seven-fold increase in the number of cancers found within a year. Galleri detected approximately three times as many cancers when added to standard-of-care screening for breast, cervical, colorectal, lung, and prostate cancers (USPSTF A, B, and C recommendations). Approximately three-quarters of the cancers detected by Galleri do not have standard of care screening options.

More than half (53.5%) of the new cancers detected by Galleri were stage I or II and more than two-thirds (69.3%) were detected at stages I-III.

"Cancer screening saves lives, but we routinely screen for just four or five cancer types in the United States today and approximately 70% of cancer deaths come from cancers that do not have standard-of-care screening and are typically caught too late," said Nima Nabavizadeh, MD, Associate Professor of Radiation Medicine at Oregon Health & Science University. "Data from PATHFINDER 2 show that Galleri could fundamentally change our approach to cancer screening, helping to detect many types of cancer earlier, when the chance of successful treatment or even cure are the greatest."

High Performance and Low Risk of False Alarms
The Galleri test detected a cancer signal in 216 participants (cancer signal detection rate of 0.93%), and of those, cancer was diagnosed in 133 participants (cancer detection rate of 0.57%). The likelihood of receiving a cancer diagnosis following a positive test result (positive predictive value) was 61.6%, substantially higher than in the previous PATHFINDER study of Galleri.

Since PATHFINDER 2 is a prospective clinical trial where the cancer status of participants is unknown at the outset, episode sensitivity – the ability to detect cancer that could be confirmed within 12 months after the blood draw – is a performance measure of the study. Galleri demonstrated strong performance, with 73.7% episode sensitivity for the 12 cancers responsible for two-thirds of cancer deaths in the U.S. For all cancers, episode sensitivity was 40.4%. Specificity was 99.6%, translating to a false positive rate of only 0.4%.

"Any multi-cancer early detection test used for population screening should aim to detect as many aggressive cancers as possible before symptoms arise and maximize the likelihood that a positive test result is actually cancer. The PATHFINDER 2 results demonstrate that the Galleri test is doing just that, increasing the number of cancers detected more than seven-fold when added to recommended screening for breast, cervical, colorectal, and lung cancers, and with a very low false positive rate," said Ofman. "What's especially promising is that Galleri showed strong sensitivity at detecting many of the cancers responsible for the majority of cancer deaths, which we believe provides clinicians with a clinically valuable and validated screening tool."

High Accuracy of Cancer Signal Origin Enabled Efficient Diagnostic Evaluation

A key benefit of Galleri is its ability to predict where in the body the cancer is coming from. The PATHFINDER 2 study demonstrated that the test correctly identified the Cancer Signal Origin (CSO) 92% of the time, leading to efficient diagnostic workups. Diagnostic resolution took a median of 46 days, and only 0.6% of all participants had an invasive procedure (159/25,114). Invasive procedures were two times more common in participants with cancer than in those without.

MCED test safety was evaluated in an analyzable cohort of 25,114 participants. No serious, study-related adverse events were reported during the diagnostic workup.

Data from this study will be submitted to the U.S. Food and Drug Administration (FDA) as part of the Galleri premarket approval (PMA) application, along with data from the prevalent screening round of the NHS-Galleri trial. In addition, GRAIL will submit to the FDA a bridging analysis 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. GRAIL expects to complete the PMA modular submission for Galleri, which is under a Breakthrough Device Designation, in the first half of 2026.

Conference call and webcast with the investment community
GRAIL management will host a conference call and webcast on Oct. 20 at 5 a.m. PT / 8 a.m. ET to discuss results of the PATHFINDER 2 study. A link to the live webcast and recorded replay will be available at the investor relations section of GRAIL's website at investors.grail.com.

Please register for the live event at this link.

To ensure timely connection, please register for the teleconference and join the webcast at least ten minutes before the scheduled start of the call. The live webcast and recorded replay are open to all interested parties.

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 performance 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 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, Galleri can detect more than 50 types of cancer before symptoms appear — when they can be easier to treat and are potentially curable[2]. Galleri is the only available MCED test with demonstrated performance in patients screened for cancer[2,*]. The Galleri test increases the number of cancers detected seven-fold when added to recommended screening for breast, cervical, colorectal and lung cancers, and has the lowest false positive rate of any MCED test on the market[1,2,3,4,**]. When a cancer signal is found, Galleri provides a cancer signal of origin with high accuracy to help guide an efficient diagnostic work-up[4,5,6]. 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.

* The Galleri test performance metrics were derived from the outcomes of an interventional clinical study of patients presenting for screening without clinical suspicion of cancer, a study population that reflects the intended use population.

** Test performance metrics do not represent results of a head-to-head comparative study. Separate studies have different designs, objectives, and participant populations, which limits the ability to draw conclusions about comparative performance.

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 GRAIL, Inc. (the "Company"), include the benefits and use of the Galleri test, the potential of the Galleri MCED test, expectations regarding the final results of the PATHFINDER 2 study, upcoming events and presentations, the timeline and results of a bridging analysis to the FDA, the applicability of the PATHFINDER 2 results to the commercial or FDA versions of the Galleri test, and the timeline for completion of the PMA modular submission.

These statements are only predictions based on the Company's current expectations and projections about future events and trends. There are important factors that could cause 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 the Company's Annual Report on Form 10-K for the period ended December 31, 2024 and Quarterly Reports on Form 10-Q for the periods ended March 31, 2025 and June 30, 2025. Moreover, the Company operates in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for the Company's management to predict all risks, nor can the Company assess the impact of all factors on its 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.

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

References:

1. Nabavizadeh N, et al. Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended-Use Population: Initial Results from the Registrational PATHFINDER 2 Study. Proffered Presentation Presented at: European Society for Medical Oncology (ESMO) Annual Meeting; October 17-21, 2025; Berlin, Germany.
2. Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. Ann Oncol. 2021 Sep;32(9):1167-77. doi: 10.1016/j.annonc.2021.05.806
3. GRAIL, Inc. False positive rate. [Data on file: GR-2025-0256]
4. Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. Lancet. 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2
5. GRAIL, Inc. Enhanced Cancer Signal Origin prediction. [Data on file: VV-TMF-59592]
6. Hackshaw A, et al. Cancer Cell. 2022;40(2):109-13.

View original content to download multimedia:https://www.prnewswire.com/news-releases/grail-pathfinder-2-results-show-galleri--multi-cancer-early-detection-blood-test-increased-cancer-detection-more-than-seven-fold-when-added-to-uspstf-a-and-b-recommended-screenings-302588036.html

SOURCE GRAIL, Inc.

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