GRAIL Presents PATHFINDER 2 Results of More Than 35,000 Participants Showing the Galleri® Test Substantially Increased Cancer Detection With Robust Performance and Favorable Safety at 2026 ASCO Annual Meeting

May 31, 2026

The Galleri Multi-Cancer Early Detection (MCED) Test Increased Cancer Detection 6.5 Fold When Added to Recommended Screenings for Breast, Colorectal, Cervical and Lung Cancer

71% of the New Cancers Detected by the Galleri Test Were in Stages I-III

MENLO PARK, Calif., May 31, 2026 /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 the analysis of the full 35,878 cohort of its registrational PATHFINDER 2 study are being presented during an oral session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting[1].

The PATHFINDER 2 study evaluated the safety and performance of the Galleri® multi-cancer early detection (MCED) test when used alongside standard-of-care cancer screenings in the U.S. and Canada. The prospective PATHFINDER 2 study is the largest interventional study of an MCED in North America to date and includes 35,878 participants in a broad, intended-use population of adults aged 50 and older with no clinical suspicion of cancer.

"Cancer outcomes depend not only on better treatments, but on finding cancer before it advances and spreads. Earlier detection can open the door to more treatment options at any stage and increase the chance for cure," said Josh Ofman, MD, MSHS, President and CEO-Elect at GRAIL. "These PATHFINDER 2 results add to the growing body of clinical evidence in a large, representative intended-use population showing that the Galleri test can meaningfully increase cancer detection beyond recommended screening with strong performance and a highly favorable safety profile. Along with the NHS-Galleri trial results, these findings reinforce the clinical benefit of Galleri and its potential to transform early cancer detection at population scale."

Galleri Increases the Number of Cancers Detected and Can Detect Them Early

While effective screening improves early cancer detection, in the U.S., only 14% of all cancers are detected by guideline-recommended screening tests[2]. In PATHFINDER 2, 60% of diagnosed cancers were screen-detected (264/440). Adding Galleri to recommended screenings for breast, cervical, colorectal, and lung cancers (USPSTF A and B recommendations) led to a 6.5 fold increase in the number of cancers found by screening. Galleri detected nearly 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).

More than half (53.0%) of the new cancers detected by Galleri were stage I or II, and 71.3% of these have no USPSTF A and B recommended screening. More than two-thirds (70.9%) of the new cancers detected by Galleri were detected at stages I-III, when treatment with curative intent is more often possible.

"PATHFINDER 2 provides important additional data on the performance and safety of MCED testing," said Karthik Giridhar, M.D., assistant professor of oncology at Mayo Clinic and a principal investigator on the PATHFINDER 2 study. "MCED tests are not a replacement for existing screening, but they have the potential to complement current approaches by helping detect cancer signals across multiple cancer types, including some for which routine screening is not currently available."

Robust Performance Metrics Consistent with Previous Studies

The Galleri test detected a cancer signal in 287 participants, and of those, cancer was diagnosed in 173 participants. The likelihood of receiving a cancer diagnosis following a positive test result (positive predictive value or PPV) was 60.3%, consistent with previously reported initial results of PATHFINDER 2 and higher than the first PATHFINDER study.

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 evaluated in the study. Galleri demonstrated strong performance, with 69.8% episode sensitivity for the 12 cancers responsible for two-thirds of cancer deaths in the U.S. For all cancers, episode sensitivity was 39.3%.

Specificity was 99.6%, translating to a false positive rate of less than 0.4%.

"The up to 6.5 fold improvement in screen-detected cancers with Galleri in PATHFINDER 2 study, coupled with the greater than 20% reduction in Stage 4 cancers observed in the NHS-Galleri trial, is really exciting data that help support Galleri's performance in a diverse and representative population," said Nima Nabavizadeh, MD, Associate Professor of Radiation Medicine at Oregon Health & Science University. "As an oncologist, I have seen too many patients diagnosed only after their cancer has spread, when treatment decisions become more difficult. By helping find more cancers earlier, when more treatment options may be available, there is great potential for multi-cancer early detection to transform cancer screening."

Galleri Pinpoints Cancer Signal Origin Allowing Efficient Diagnostic Workups

A key benefit of the Galleri test is its ability to predict where in the body the cancer signal is coming from. The PATHFINDER 2 study demonstrated that the test correctly identified the Cancer Signal Origin (CSO) 91.3% of the time, leading to efficient diagnostic workups. Diagnostic resolution took a median of 48 days, and only 0.6% of all safety-analyzable participants had an invasive procedure (213/35,335) following a positive MCED test result. A total of 90.5% of invasive procedures were nonsurgical.

Screening with the Galleri test had a favorable safety profile, with a low false-positive rate and a low rate of invasive procedures. There were five study-related adverse events reported during diagnostic evaluation, only in those with cancer diagnosis. Anxiety temporarily increased for participants with a positive MCED test and subsequent cancer diagnosis, and returned to baseline by 12 months, as has been observed for other screening tests. One serious adverse event related to the diagnostic work-up was identified after the data lock. Follow-up is ongoing; this and any other findings after data lock will be reported in full in the next interim analysis.

About PATHFINDER 2 (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), episode 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, Calif. 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 (MCED) test screens for more than 50 cancer types, including many deadly cancers that currently lack screening options, such as pancreatic, ovarian and liver/bile duct cancers[3]. The Galleri test is the only MCED test clinically proven through a randomized controlled trial to increase earlier cancer detection (Stage I-III) and reduce Stage IV diagnoses - enabling more patients to have curative treatment[4]. When added to standard-of-care screening, the Galleri test reduced Stage IV diagnosis by more than 20% after the first year of screening across all stageable cancers[4,*]. The Galleri test increased cancer detection by screening four times versus standard of care screening alone[4]. The Galleri test has the lowest false positive rate among MCED tests** and the ability to predict the Cancer Signal of Origin with greater than 90% accuracy, helping guide efficient diagnostic evaluation[1,4,[5]]. The Galleri test is backed by a robust evidence program, with more than 380,000 participants across multiple studies, including the NHS-Galleri trial, the first and only randomized controlled trial for an MCED test. The Galleri test has delivered consistent performance across these studies. 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.

*A statistically significant reduction was not observed in combined stage III–IV diagnoses across three screening rounds for the 12 deadly cancers.

**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.

GRAIL 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 related to the potential benefits, uses and impacts of the Galleri test, extrapolation of trends in the results, comparability of the results to a real world setting, benefits of population screening with Galleri, the applicability of the PATHFINDER 2 results to the commercial or FDA versions of the Galleri test, and plans to submit the results for publication, among others.

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-K for the period ended December 31, 2025. 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, financial condition and success in our business strategies and operations 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.

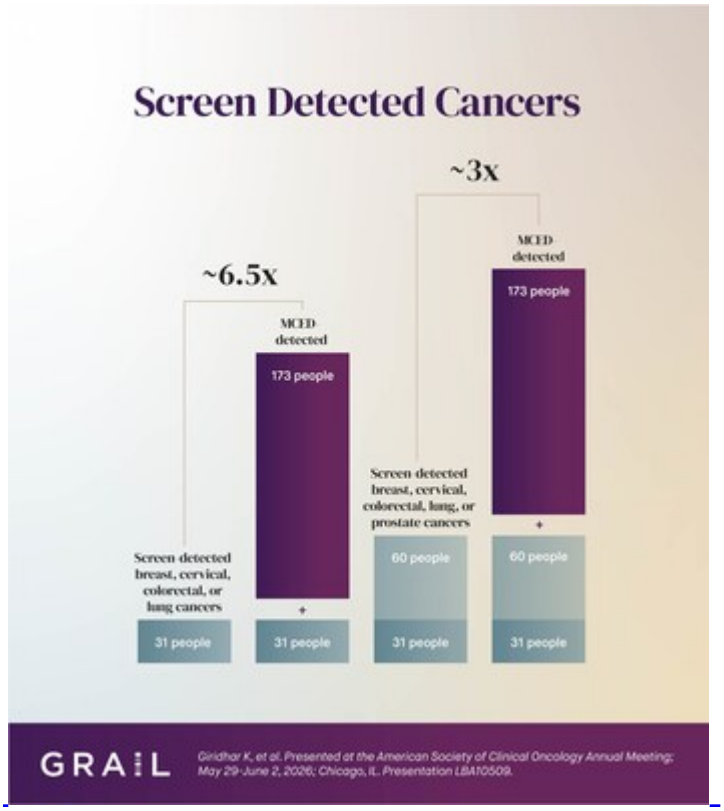
[1] Giridhar K, et al. Safety and Performance Results From PATHFINDER 2 (PF2), a Registrational Study of a Multi-Cancer Early Detection (MCED) Test in an Intended-Use Population [presentation]. American Society of Clinical Oncology (ASCO) Annual Meeting; 2026 May 29-June 2

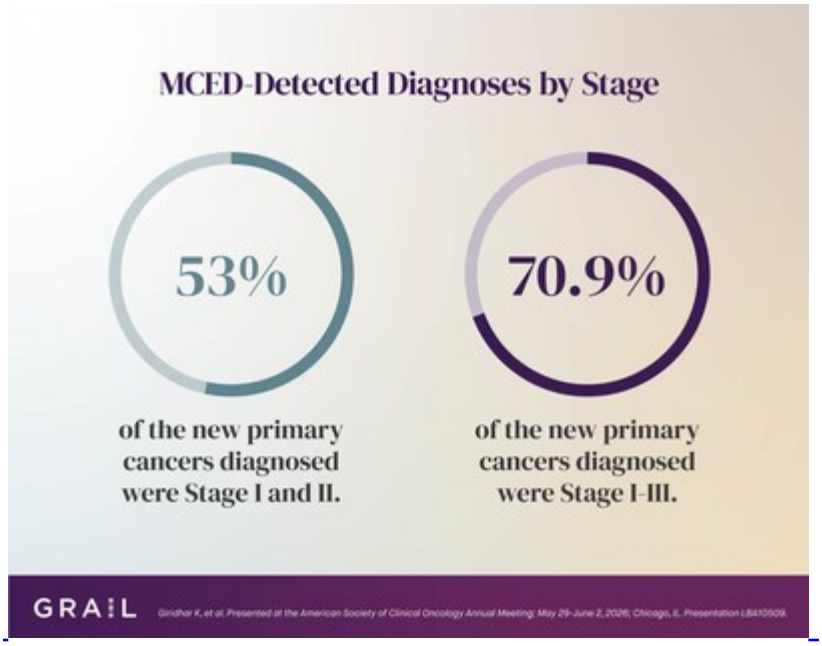
[2] NORC at the University of Chicago. Percent of cancers detected by screening in the U.S. https://cancerdetection.norc.org/ (2022).

[3] 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

[4] Swanton C. NHS-Galleri: Primary Results From a Randomised Controlled Trial to Assess the Clinical Utility of a Multi-Cancer Early Detection (MCED) Test in Population Screening [presentation]. American Society of Clinical Oncology (ASCO) Annual Meeting; 2026 May 29-June 2.

[5] GRAIL, Inc. False positive rate. [Data on file: GR-2025-0256]





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