Landmark NHS-Galleri Trial Demonstrates a Substantial Reduction in Stage IV Cancer Diagnoses, Increased Stage I and II Detection of Deadly Cancers, and Four-Fold Higher Cancer Detection Rate

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The Primary Endpoint of Statistically Significant Combined Stage III-IV Reduction Was Not Met, However A Favorable Trend Was Observed Over Time

GRAIL Announces U.S. Sales Force Expansion Based on Strong NHS-Galleri and PATHFINDER 2 Trial Results

MENLO PARK, Calif. and LONDON, Feb. 19, 2026 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced topline results from the landmark, randomized, controlled NHS-Galleri trial, which evaluated annual multi-cancer screening with the Galleri® test in England's National Health Service (NHS) over three years in 142,000 demographically representative participants aged 50 to 77.

The clinical performance of Galleri has been rigorously established in several studies, and the NHS-Galleri trial was designed to demonstrate population-level impact through the reduction of late stage cancer diagnoses and increased cancer detection rate within the NHS to inform a decision about a national screening program in England. For the US market, the Galleri premarket approval application pending review by the FDA also includes metrics from the NHS-Galleri trial that are focused on test performance, clinical validation, and the clinical benefit of detection at Stages I through III, including reduction in Stage IV cancer diagnoses.

Key trial results include:

- The primary endpoint of statistically significant Stage III-IV reduction was not observed. However, there was a favorable trend toward fewer Stage III-IV cancers in a pre-specified group of 12 deadly cancers* in the intervention arm after the prevalent screening round.
- Adding Galleri to standard of care screening resulted in a substantial and clinically meaningful reduction in Stage IV diagnoses compared with standard of care alone across the pre-specified group of 12 deadly cancers. Stage IV diagnoses in these cancers decreased with each year of sequential screening, with a greater than 20% reduction in the second and third rounds. Similar reductions were observed across all cancers.
- Annual screening with the Galleri test plus standard of care screening resulted in a four-fold improvement in the overall cancer detection rate compared to standard of care screening alone in England for breast, colorectal, cervical and high risk lung cancer.
- Substantial increase in the absolute number of Stage I-II cancers in the 12 pre-specified deadly cancer types that are typically found in late stages were observed in the intervention arm.
- Screening with the Galleri test resulted in a substantial reduction in the number of cancers detected clinically through emergency presentation, which are associated with significantly higher mortality and healthcare costs.

"The NHS-Galleri trial provides the strongest evidence to date that multi-cancer early detection can shift the stage at which cancers are detected at a population level," said Bob Ragusa, Chief Executive Officer at GRAIL. "We are excited to see the substantial reduction in Stage IV cancer diagnoses, as well as the continued strong Galleri test performance metrics. Based on these promising data, as well as the exciting PATHFINDER 2 results, we are expanding our field-based sales and medical teams to bolster our education efforts and support growing demand."

"As an oncologist, I see how profound the difference is between Stage III and Stage IV disease," said Professor Charles Swanton, thoracic medical oncologist at University College Hospital, London and one of the NHS-Galleri trial's chief investigators. "When cancer is detected before distant metastatic spread, we can often treat with curative intent, combining surgery, radiotherapy, and systemic therapy in an effort to eradicate all disease.

Once distant metastases are established, treatment typically shifts toward long-term disease control and symptom management; durable cures become uncommon in most solid tumours. Reducing the proportion of patients diagnosed with metastatic disease is therefore not merely a statistical aim, it dramatically increases the number of patients for whom eradication of disease and cure is possible."

The Galleri test's performance – positive predictive value (PPV), specificity and Cancer Signal of Origin (CSO) accuracy – was consistent with the range previously reported from GRAIL's North American studies.

Importantly, no serious safety concerns were reported in participants who received the Galleri test in the NHS-Galleri trial.

"The design of the NHS-Galleri trial was informed by a growing body of evidence showing that, across multiple cancer types, reductions in late-stage disease are strongly associated with reductions in cancer mortality. The reduction in Stage IV cancer diagnoses is an exciting and critically important outcome, which we believe can lead to more effective intervention for patients, particularly given the substantial and growing arsenal of effective treatments for many Stage III cancers," said Sir Harpal Kumar, Chief Scientific Officer and President, International at GRAIL. "We are deeply grateful to the more than 142,000 participants who took part in this study, as well as to the NHS, the Cancer Prevention Trials Unit at Queen Mary University of London, Cancer Alliances, investigators, and clinical teams whose dedication made this landmark trial possible. Our learnings from this trial enrich our understanding of cancer biology, multi-cancer screening, and the importance of implementation, particularly ensuring rapid and thorough diagnostic investigation after a positive test result."

Additional analyses are underway to better understand these rich data, and detailed results will be submitted for presentation at the ASCO 2026 Annual Meeting. Of note, there was a higher than anticipated incidence of Stage III cancers in the NHS-Galleri trial. In both the US and the NHS data, the time to diagnostic resolution appears to improve over time as physicians gain experience with the Galleri test and diagnostic workup. The number and distribution of cancer stages across screening rounds suggests the potential for a stronger effect with longer follow up as data matures, and GRAIL plans to extend the trial's follow up period by 6-12 months.

*The 12 cancer types include anus, bladder, colorectal, esophagus, head and neck, liver/bile duct, lung, lymphoma, myeloma/plasma cell neoplasm, ovary, pancreas, stomach.

About the NHS-Galleri Trial (NCT05611632; ISRCTN91431511)
The NHS-Galleri trial is the first and largest prospective, randomized, controlled trial to assess the clinical utility and performance of a multi-cancer early detection test for population screening when added to standard care. The trial recruited more than 140,000 asymptomatic participants, aged 50 to 77, and was conducted in partnership with the NHS in England. Participants provided three blood samples over two years, about 12 months apart. The primary objective of the NHS-Galleri trial is to show a reduction in late-stage (III-IV) cancers in people who received the Galleri test compared with those who did not. This will be measured in three clinically important groups of cancers, focusing first in a pre-specified group of 12 cancer types that together represent approximately two-thirds of cancer deaths in England and the United States. Secondary objectives include reduction in stage IV cancer; performance of the Galleri test, including positive predictive value and false positive rate; increase in overall cancer detection rate; safety; and healthcare resource utilization.

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.

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, our expectations regarding the final results of the NHS-Galleri trial, potential impacts of alternative or additional trial designs and analyses, planned upcoming events and presentations, the applicability of the NHS-Galleri results to the commercial or FDA versions of the Galleri test, and expectations or timelines relating to the approval of Galleri by the FDA, if at all.

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 sections entitled "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2024 and in our Quarterly Report on Form 10-Q for the period ended September 30, 2025 (the "Form 10-Q"). 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.

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