GRAIL to Present New Galleri® Data From More Than 32,000 Participants Across the PATHFINDER 2, SYMPLIFY and REFLECTION Studies at ESMO Congress 2025 and EDCC

September 23, 2025

First PATHFINDER 2 Results Accepted as a Late-Breaking Presentation at the European Society for Medical Oncology (ESMO) Congress 2025; Results to be Submitted to FDA as Part of the Galleri Premarket Approval Application (PMA)

Updated SYMPLIFY and REFLECTION Study Results to be Presented at the Early Detection of Cancer Conference (EDCC) Highlight Galleri Performance in Symptomatic and Veteran Populations, Respectively

MENLO PARK, Calif., Sept. 23, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, will present new data highlighting the Galleri® multi-cancer early detection (MCED) test performance and safety from its registrational PATHFINDER 2 study at the European Society for Medical Oncology (ESMO) Congress 2025 in Berlin, Oct. 17-21, 2025. The PATHFINDER 2 study, conducted under an FDA-approved investigational device exemption application, is the largest MCED interventional study conducted in the U.S. in an intended use population with no clinical suspicion of cancer.

As previously reported, top-line results from evaluable PATHFINDER 2 study participants with 12 months of follow-up showed that adding the Galleri test to standard of care screening demonstrated substantially greater additional cancer detection, as well as a substantially higher positive predictive value (PPV), than observed in the first PATHFINDER study. Cancer signal of origin (CSO) accuracy and specificity were consistent with the PATHFINDER study.

In addition, the company will present new Galleri data from the follow-up of symptomatic participants enrolled in SYMPLIFY, a prospective observational study, and real world experience of veterans tested with Galleri from the REFLECTION study at the Early Detection of Cancer Conference (EDCC) 2025 in Portland, Ore., Oct. 21-23, 2025.

"Galleri is the only available MCED test with demonstrated performance in an intended use population being screened for cancer. These new data build on the results from our first clinical implementation study, PATHFINDER, which was published in the *Lancet* in 2023, and showed that Galleri approximately doubled the number of cancers identified when added to standard of care screening," said Josh Ofman, MD, MSHS, President of GRAIL. "We're witnessing the beginning of a transformative era for cancer screening, with these results demonstrating Galleri's ability to detect cancers earlier, when they can be easier to treat and are potentially curable."

ESMO Data Presentations

Title: Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended-Use Population: Initial Results from the Registrational PATHFINDER 2 Study

Abstract Number: 7528
Session Title: Proffered Paper session 1: Basic science & Translational research
Date/Time: Saturday, Oct. 18, 2025 at 10:15-10:25 a.m. CEST
Location: Nuremberg Auditorium - Hall 5.2

Title: Clinical Performance of a Blood-only, Targeted Methylation Circulating Tumor DNA (ctDNA) Assay for Minimal Residual Disease (MRD) Detection in Colorectal Cancer (CRC)

Abstract Number: 6215
Presentation Type: e-Poster

EDCC Data Presentations

Title: Long-term cancer registry follow-up of false positive multi-cancer early detection (MCED) test results from the SYMPLIFY study.

Presentation Type: Poster

Title: REFLECTION: Real-World Evidence Study of Multi-Cancer Early Detection (MCED) Among Veterans in the Veterans Affairs Healthcare System (VA)

Presentation Type: Lightning Talk
Date/Time: Thursday, Oct. 23, 10:35-10:50 AM PT

Title: NHS-Galleri trial: approaches to retain a diverse participant cohort across multiple trial appointments

Presentation Type: Poster

Title: Baseline participant characteristics from PATHFINDER 2, a prospective interventional study of a multi-cancer early detection test in a population setting

Presentation Type: Poster

Title: Molecular Cancer Signal Localization in Multi-Cancer Early Detection (MCED) Testing Minimizes Radiation and Imaging Burden Compared to Whole Body Imaging Approaches

Presentation Type: Poster

More information about timing of the EDCC presentations can be found here.

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 test, Galleri can detect more than 50 types of cancer before symptoms appear — when they can be easier to treat and are potentially curable. Galleri is the only available MCED test with demonstrated performance in patients screened for cancer.* The Galleri test approximately doubles the number of cancers detected when added to standard of care screening and has the lowest false positive rate of any MCED test.** When a cancer signal is found, Galleri provides a cancer signal of origin with high accuracy to help guide an efficient diagnostic work-up. 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 us, include the benefits and use of the Galleri test, the potential of the Galleri MCED test, upcoming events and presentations, expectations about the market for MCED tests and other statements.

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 June 30, 2025 and our Form 10-K for the period ended December 31, 2024. 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.

32-000-participants-across-the-pathfinder-2--symplify-and-reflection-studies-at-esmo-congress-2025-and-edcc-302563434.html

SOURCE GRAIL, Inc.

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