GRAIL and University of Oxford to Present Long-Term Data From the SYMPLIFY Study Evaluating the Galleri® Multi-Cancer Early Detection Test in Symptomatic Individuals at the Early Detection of Cancer Conference (EDCC)

October 20, 2025

One-Third of Participants Initially Believed to Have a False-Positive Result Were Later Diagnosed With Cancer During Follow Up

Updated Positive Predictive Value of Galleri in This Symptomatic Population was 84.2%

Galleri Accurately Predicted the Location of the Cancer in Almost All Cases Initially Considered as False Positives, Reinforcing the Value of Galleri's CSO Capability

MENLO PARK, Calif. and OXFORD, United Kingdom, Oct. 20, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, and the University of Oxford, today announced that positive long-term results from an extended registry follow-up of the SYMPLIFY study will be presented on Oct. 21 at the Early Detection of Cancer Conference (EDCC) in Portland, Oregon.

SYMPLIFY, a prospective observational study, is the first large-scale evaluation of a multi-cancer early detection (MCED) test in individuals who presented with symptoms to primary care and were referred for diagnostic follow-up for suspicion of cancer. In SYMPLIFY, the Galleri® test was used to assess blood samples from more than 6,000 participants with symptoms of cancer who followed standard diagnostic pathways. However, as a non-interventional study, the results of the tests were unknown to physicians and did not inform the approach to diagnosis. No MCED results were returned to participants or their clinicians during the study.

"The conversion of false positive results to cancer diagnosis in this updated analysis of the SYMPLIFY study highlights the importance of proactive follow-up on positive MCED results, as one third of the apparent false positive results were actually cancers the standard-of-care diagnostic process couldn't immediately identify," said Brian D. Nicholson, MRCGP, DPhil, Associate Professor at the Nuffield Department of Primary Care Health Sciences, University of Oxford, United Kingdom and co-lead investigator of the study. "Additionally, the results underscore the value of Galleri's Cancer Signal Origin prediction, which aligned with the eventual diagnosis in almost all of the cases initially considered to be false positives. We are pleased to present these data at EDCC and have submitted this analysis for full publication."

Previous SYMPLIFY results showed potential of MCED testing in people with symptoms suggestive of cancer

Most people diagnosed with cancer visit primary care with symptoms before diagnosis[1]. Many of these people report common, non-specific symptoms such as bloating, unexplained weight loss or abdominal pain, which can be attributed to various conditions as well as cancer[2].

The primary analysis of the SYMPLIFY study, previously published in *The Lancet Oncology*, supported the feasibility of using the Galleri test to assist clinicians with decisions regarding referral from primary care. In that analysis, which followed participants until diagnostic resolution or up to nine months, Galleri's positive predictive value (PPV) was 75.5%. When a cancer signal was detected, the test accurately predicted the Cancer Signal Origin (CSO) in 84.8% of cases.

Updated results demonstrate importance of continued follow-up after a cancer signal is detected

Patients reported to have a false positive Galleri result were followed for 24 months in national cancer registries for England and Wales. The analysis showed that 35.4% (28 of 79 participants) were later diagnosed with cancer within 24 months of enrollment. This reduction in false positives from 79 to 51 resulted in an increase of PPV to 84.2%. In aggregate, 27 of these 28 participants had a correct CSO prediction which could have led to a faster or more efficient diagnosis. In more than half of these cases, the cancer type diagnosed was not congruent with the original diagnostic clinic to which the patient was referred by the general practitioner based on the clinical presentation:

- 16 of the 28 (57.1%) were diagnosed with cancer within nine months of enrollment.
  - Eight of the 16 (50%) were diagnosed with cancers that were correctly predicted by the Galleri test's CSO finding, but were incongruent with the diagnostic pathway chosen by the general practitioner based on the participants' presenting symptoms.
- 12 of the 28 (42.9%) were diagnosed 10-24 months after enrollment.
  - Seven of the 12 (58.3%) were diagnosed outside the original referral pathway; in those cases, the CSO also was correct, matching the site that was ultimately diagnosed.

"The SYMPLIFY study, focused on patients presenting with symptoms, adds to the breadth of our clinical experience in asymptomatic populations. This robust data demonstrates the potential benefit of the Galleri test as a diagnostic tool for individuals presenting with symptoms of cancer, particularly where those symptoms are non-specific. The fact that, in all but one of the additional patients diagnosed with cancer, a Galleri CSO prediction correctly identified the cancer type, including in many cases where the symptoms were non-specific, further reinforces the value of the Galleri test's CSO capability," said Sir Harpal Kumar, President, International Business & BioPharma at GRAIL. "Furthermore, the 24-month follow-up data being presented at EDCC underscore the importance of continued follow-up to help identify cancers that may initially be missed in diagnostic evaluation. These latest results add to the body of evidence that Galleri could support clinical decision-making in primary care for referral to urgent diagnostic investigations of cancer and drive more efficient use of diagnostic capacity."

About the SYMPLIFY Study
SYMPLIFY is a prospective multicentre observational study and represents the first large-scale evaluation of an MCED test in symptomatic patients who were referred from the primary care setting due to clinical suspicion of cancer. The study enrolled 6,238 patients, aged 18 years and older, in England and Wales who were referred for urgent imaging, endoscopy or other diagnostic modalities to investigate symptoms suspicious for possible cancer. Of the total enrolled patients, there were 5,461 evaluable patients who achieved diagnostic resolution. GRAIL's MCED test was performed in batches, blinded to clinical outcome, and results were compared with the diagnosis obtained by standard of care pathways to assess the test's performance.

The University of Oxford sponsored the SYMPLIFY study and was responsible for data collection, analysis and interpretation. The study was funded by GRAIL with support from National Health Service (NHS) England, NHS Wales, the National Institute for Health and Care Research (NIHR) and NIHR Oxford Biomedical Research Centre.

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[3]. Galleri is the only available MCED test with demonstrated performance in patients screened for cancer[3,*]. 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[5,7,8,**]. 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 us, include the benefits and use of the Galleri test, the potential of the Galleri MCED test, and upcoming events and presentations.

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 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.

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