Patient Reported Outcomes for GRAIL's Galleri® Multi-Cancer Early Detection Blood Test Published in Lancet Oncology

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Analysis of Patient Reported Outcomes From PATHFINDER Indicate Minimal Patient Distress Associated with Multi-Cancer Early Detection Testing

MENLO PARK, Calif., Jan. 13, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL) a healthcare company whose mission is to detect cancer early when it can be cured, today announced that patient-reported outcomes (PRO) assessing patient perspectives from the PATHFINDER study were published in *Lancet Oncology*. The PATHFINDER study included secondary and exploratory outcomes with the objective of assessing PRO and perceptions of multi-cancer early detection (MCED) testing.

PRO assessment was conducted for eligible PATHFINDER study participants with either a cancer signal detected (CSD) or no cancer signal detected (NCSD) over a 12-month follow-up period. In the PATHFINDER study, general anxiety, distress and uncertainty after results disclosure, health-related quality of life, satisfaction with the Galleri® test, and intent towards guideline-recommended screening and repeat MCED testing were assessed. Three instruments used to assess PRO included an adapted Multidimensional Impact of Cancer Risk Assessment (MICRA) for distress, uncertainty and positive experience at MCED test result disclosure, PRO Measurement Information System (PROMIS) Anxiety short-form for anxiety symptoms, the Short Form 12-Item Health Survey (SF-12v2) for health-related quality of life, and a satisfaction questionnaire.

"Previous studies have shown that there is a temporary increase in anxiety symptoms after cancer screening, particularly for those with a test result indicating they may have cancer," said Lincoln Nadauld, MD, lead author of the study and was vice president, chief of Precision Health & Academics at Intermountain Health during the PATHFINDER study and currently CEO at Culmination Bio, Inc. "PRO results in the PATHFINDER study were consistent with other studies and showed the transient nature of the anxiety increase coupled with satisfaction with the screening and commitment to continue their standard screenings along with MCED testing. These encouraging results indicate that MCED could be a valuable tool for early detection with minimal distress for patients."

Overall the study demonstrated minimal patient distress associated with MCED testing. Most participants with a NCSD result responded that they were "relieved about my test result." The negative patient-reported impacts associated with a CSD test result were small and returned to baseline within 12 months. High overall satisfaction with the MCED test was reported across participant groups regardless of signal detection status and eventual diagnosis. Most participants reported they were "likely"/"very likely" to adhere to future guideline recommended screening tests as recommended by their healthcare provider.

"As the pioneer in multi-cancer early detection, GRAIL is committed to not only evaluating the performance of the Galleri test but also the impact of MCED screening on patients," said Eric Klein, MD, Distinguished Scientist at GRAIL and co-author on the study. "Collecting participant perspectives and appropriately supporting recipients of cancer screening may improve adherence rates and early detection. The patient-reported outcome findings from the PATHFINDER study suggest MCED testing is associated with a high level of satisfaction."

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, the Galleri test can identify DNA shed by cancer cells, which can act as a unique "fingerprint" of cancer, to help screen for some of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, liver, and others.* The Galleri test can be used to screen for cancer before a person becomes symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test can indicate the origin of the cancer, giving healthcare providers a roadmap of where to explore further. 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.

Sensitivity in study participants with –
Pancreas cancer: 83.7% overall (61.9% stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). Esophagus cancer 85.0% overall (12.5% stage I, 64.7% stage II, 94.7% stage III, 100% stage IV). Ovary cancer: 83.1% overall (50.0% stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV).

Liver/bile duct cancer: 93.5% overall (100% stage I, 70.0% stage II, 100% stage III, 100% stage IV).

Important Galleri Safety Information
The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri 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, may include statements about extrapolation of data, expectations and projections of performance and impact of future tests or products, technology, clinical studies, regulatory compliance, future investment and strategy and anticipated trends in our business.

These statements are only predictions based on GRAIL's 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 discussed under the section entitled "Risk Factors" in GRAIL's most recent Quarterly Report on Form 10-Q filed with the SEC. Moreover, GRAIL operates in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for GRAIL's management to predict all risks, nor can they assess the impact of all factors on GRAIL's 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 GRAIL 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 GRAIL's control. Although GRAIL believes the expectations and projections expressed or implied by the forward-looking statements are reasonable, GRAIL cannot guarantee future results, level of activity, performance, or achievements. GRAIL's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, GRAIL undertakes no obligation to update any of these forward-looking statements after the date of this press release to conform its prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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