Results of GRAIL's Galleri® Multi-Cancer Early Detection Blood Test in Prostate Cancer Published in JCO Precision Oncology

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Data Support Clinical Performance of Galleri to Detect More Aggressive Prostate Cancers

MENLO PARK, Calif., Aug. 29, 2024 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL) a healthcare company whose mission is to detect cancer early when it can be cured, today announced that detailed findings of the performance of its Galleri® multi-cancer early detection (MCED) test in prostate cancer were published in *JCO Precision Oncology*. The data support the clinical performance of the Galleri test to preferentially screen for aggressive, clinically significant prostate cancer as compared to slow-growing (indolent) cases in the Circulating Cell-free Genome Atlas (CCGA) and PATHFINDER studies.

"All screening tests run the risk of overdiagnosis. In the case of prostate cancer, this is largely due to the high prevalence of low-grade, indolent cancers," said Brandon Mahal, M.D., a radiation oncologist at Sylvester Comprehensive Cancer Center, part of the University of Miami Miller School of Medicine, and lead author of the study. "The results of this study demonstrate that the use of MCED tests in a population-based screening program is unlikely to contribute to overdiagnosis of slow-growing prostate cancers that may not need treatment. That being said, clinically validated MCED tests like Galleri reveal that when a prostate cancer signal is detected, it usually indicates aggressive disease and additional diagnostic evaluation is necessary."

The published data is from an analysis of 420 prostate cancer patients identified in the independent clinical validation portion (substudy 3) of the multi-center, case-control observational study Circulating Cell-free Genome Atlas (CCGA) study and 18 cases from the prospective intended-use PATHFINDER study. The data were previously presented at the American Association for Cancer Research (AACR) Annual Meeting in March 2024.

Results from this analysis showed that of the prostate cancers that were detected by the MCED test, most were clinically significant (93% were intermediate or high grade and 67% were stage III or IV). For detected prostate cancers, the cancer signal of origin (CSO) prediction accuracy was > 90%. Detectability for stage I and II cancers were 4.2% across both studies combined, which is expected with low shedding prostate cancer tumor fraction and is consistent with cfDNA literature in prostate cancer. Test sensitivity of prostate cancer for all stages was 11.2% in substudy CCGA-3. Notably, the MCED test detected no low-grade cancers, 1.9% of intermediate-grade cancers, and only 4.2% of stage I and II cancers across both studies combined. Of the detected cases, 93% were Gleason grade groups 3-5. This analysis demonstrates the MCED test preferentially detects high-grade, clinically significant prostate cancer. This is important because an MCED test, when used in addition to standard-of-care screening, should not exacerbate overdiagnosis of indolent cancers. These findings also suggest that individuals with a cancer signal detected and a prostate CSO prediction should undergo a prompt diagnostic evaluation to determine the presence of aggressive disease for which treatment is generally indicated[1].

"This prostate cancer analysis underscores the power of Galleri in a general population of men at-risk for prostate cancer as it is able to detect biologically significant cancers that need treatment without potentially contributing to the burden of overdiagnosis," said Dr. Eric Klein, Distinguished Scientist at GRAIL and an author on the study. "The very high accuracy of the cancer signal origin prediction for prostate cancer indicates the need for a prompt diagnostic work-up in those with a cancer signal detected."

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. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate from Illumina Inc. under the terms of the Interim Measures Order of the European Commission.

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
GRAIL's 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 U.S. Food and Drug Administration. GRAIL's 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 expectations and projections of future tests or products, technology, clinical studies, regulatory compliance, potential market opportunity, anticipated growth strategies, and anticipated trends in our business.

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 discussed under the section entitled "Risk Factors" in the Registration Statement on Form 10 filed by GRAIL (the "Form 10"), as may be further amended. 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.

This press release shall not constitute an offer of any securities for sale, nor shall there be any offer, sale or distribution of securities in any jurisdiction in which such offer, sale or distribution would be unlawful prior to appropriate registration or qualification under the securities laws of such jurisdiction.

References

1. "Initial Treatment of Prostate Cancer, by Stage and Risk Group." American Cancer Society, 22 Nov. 2023, www.cancer.org/cancer/types/prostate-cancer/treating/by-stage.html.

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