Grail to Present New Multi-Cancer Early Detection Data at the 2023 ASCO Annual Meeting

May 22, 2023

Data Include Interim Results From the SYMPLIFY Study Evaluating GRAIL's Multi-Cancer Early Detection Test in Symptomatic Patients Referred for Cancer Suspicion

Clinical and Real-World Experience Analyses Highlight Performance and Implementation of the Galleri® Multi-Cancer Early Detection Test

MENLO PARK, Calif., May 22, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, will present new data evaluating the use and potential of its methylation-based multi-cancer early detection (MCED) platform at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 2-6. Presentations include interim results from SYMPLIFY, the first large-scale prospective study to evaluate GRAIL's MCED test in symptomatic patients referred for cancer suspicion, as well as Galleri ® real-world clinical surveillance data and subset analyses from the PATHFINDER clinical implementation study. An evaluation of Galleri implementation using a centralized model within Mercy's multi-state health system will also be presented.

"If we hope to bend the cancer mortality curve, we need a new, population-scale approach for screening people that finds many more cancers than we do today, in earlier stages when treatments are often more effective," said Josh Ofman, MD, MSHS, president at GRAIL. "We believe that adding multi-cancer early detection testing to recommended screening is the best chance to address the growing burden of late-stage cancer in an aging population. We are excited to present new data at this year's ASCO Annual Meeting supporting the use of GRAIL's MCED technology in adults at elevated risk of cancer, as well as initial findings from SYMPLIFY, a study evaluating patients presenting with signs and symptoms who are referred for a cancer evaluation."

Initial results from SYMPLIFY will be presented during an oral session. SYMPLIFY is the first prospective study assessing the clinical performance of GRAIL's MCED Methylation Platform in individuals with signs and symptoms that may indicate cancer. Researchers will also present an analysis of the early real-world clinical experience using the Galleri MCED test to detect a shared cancer signal and predict cancer signal of origin (CSO) to guide targeted diagnostic workup. Additionally, doctors from Mercy will present a preliminary analysis of an MCED test implementation model within a large health system utilizing a patient navigation system. A follow-up analysis to the PATHFINDER study assessing clinical implementation of the test following a cancer signal detected result and CSO-guided workups will also be presented. Results from the PATHFINDER study were previously reported during the European Society for Medical Oncology (ESMO) Congress 2022.

Abstracts will be available on the 2023 ASCO Annual Meeting website. Updated analyses will be presented at the Annual Meeting.

Oral Sessions

Title: Large-scale observational prospective cohort study of a multi-cancer early detection (MCED) test in symptomatic patients referred for cancer investigation
Session Title: Care Delivery and Regulatory Policy
Date/Time: June 3, 2023, 1:27 to 1:39 PM CDT
Location: S100a
Abstract Number: 1501

Title: Methylated DNA biomarkers and incident cancer in the American Cancer Society (ACS) Cancer Prevention Study-3 (CPS-3) cohort
Session Title: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Date/Time: June 5, 2023, 9:12 to 9:24 AM CDT
Location: Hall D2
Abstract Number: 3004

Posters

Title: Early real-world (RW) experience with a multi-cancer early detection (MCED) test
Session Title: Prevention, Risk Reduction and Hereditary Cancer
Date/Time: June 3, 2023, poster session from 1:15 to 4:15 PM CDT; panel discussion from 5:04 to 5:14 PM CDT
Location: S102
Abstract Number: 10519

Title: Clinical evaluation of cancer signal origin prediction and diagnostic resolution following multi-cancer early detection testing
Session Title: Prevention, Risk Reduction and Hereditary Cancer
Date/Time: June 3, 2023, poster session from 1:15 to 4:15 PM CDT; panel discussion from 5:04 to 5:14 PM CDT
Location: S102
Abstract Number: 10520

Title: Preclinical circulating tumor DNA (ctDNA) shedding duration and prognostic implications of modeling 3669 participants from American Cancer Society Cancer Prevention Study-3 (CPS-3) and Circulating Cell-free Genome Atlas substudy 3 (CCGA3)
Session Title: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Date/Time: June 3, 2023, 8:00 to 11:00 AM CDT
Location: Hall A
Abstract Number: 3060

Title: Elevated cancer risk among individuals with combinations of cancer-related risk factors: A large claims database analysis
Session Title: Prevention, Risk Reduction and Hereditary Cancer

Date/Time: June 3, 2023, 1:15 to 4:14 PM CDT
Location: Hall A
Abstract Number: 10561

Title: Examining the potential for lead-time bias by estimating stage-specific proportions of deaths due to diagnosed cancer
Session Title: Prevention, Risk Reduction and Hereditary Cancer
Date/Time: June 3, 2023, 1:15 to 4:15 PM CDT
Location: Hall A
Abstract Number: 10535

Title: Overall and non-lung cancer incidence in the National Lung Screening Trial (NLST) as indicators of potential for multi-cancer screening
Session Title: Prevention, Risk Reduction and Hereditary Cancer
Date/Time: June 3, 2023, 1:15 to 4:15 PM CDT
Location: Hall A
Abstract Number: 10633

Title: Methylation-based prediction of myelodysplastic syndrome survival outcomes
Session Title: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes and Allotransplant
Date/Time: June 5, 2023, 8:00 to 11:00 AM CDT
Location: Hall A
Abstract Number: 7058

Title: Implementation of a multi-cancer early detection (MCED) test using a centralized model within (w/i) a multi-state health system
Session Title: Care Delivery and Regulatory Policy
Date/Time: June 5, 2023, 1:15 to 4:15 PM CDT
Location: Hall A
Abstract Number: 1526

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 before symptoms appear and 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®
Galleri is the first-of-its-kind multi-cancer early detection (MCED) test, which can detect a shared cancer signal across more than 50 types of cancer through a routine blood draw. The Galleri test can improve the opportunity for asymptomatic early detection by screening for multiple cancers, most of which lack recommended screening tests. Supported by robust clinical evidence, it has demonstrated a low false positive rate and high positive predictive value (the proportion of people with a positive screening result who are diagnosed with cancer) in asymptomatic people at an elevated risk for cancer.

The Galleri test uses next-generation sequencing and machine-learning algorithms to isolate cell-free DNA and analyze its methylation patterns to detect if a cancer signal is present. If a cancer signal is detected, the Galleri test predicts the cancer signal origin, or the tissue or organ where the cancer signal originated, to help guide diagnostic evaluation.

The Galleri test requires a prescription from a licensed health care provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. It is intended for use in people with an elevated risk of cancer, such as those aged 50 or older.

For more information, visit galleri.com.

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 "Cancer Signal Not 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.

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