GRAIL Presents New Data on Galleri® and Its Methylation Platform at the Annual American Association for Cancer Research (AACR) Meeting

March 27, 2024

New Data Will Highlight Use of GRAIL's Targeted Methylation Platform Across Early Cancer Detection and Precision Oncology

Longer-term Data Underscore the Potential Value of GRAIL's Galleri ® for Repeat Screening for Clinically Significant Cancers

MENLO PARK, Calif., Mar. 27, 2024 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, will present new data on the clinical utility of its Methylation Platform across the cancer continuum, and the impact of multi-cancer early detection (MCED) testing in guiding diagnostic evaluation at the American Association for Cancer Research (AACR) Annual Meeting in San Diego, Calif., April 5-10, 2024.

"The data we are presenting at AACR continue to support the potential of GRAIL's Methylation Platform to transform cancer care and the potential benefits of population-scale asymptomatic (or early) cancer detection," said Jeffrey Venstrom, MD, Chief Medical Officer at GRAIL. "Our longer-term research demonstrates that adding MCED tests like Galleri to guideline-recommended screenings can help direct diagnostic evaluation and underscores the potential value of repeat MCED screening. Additionally, new data from our Methylation Platform suggests the ability to identify relevant cancer subtypes using a single blood test, helping to enable precision medicine and biomarker discovery."

In the MCED setting, GRAIL is honored to present 3 **oral presentations** at AACR:

- Demonstrating the first real-world evaluation of repeat MCED / Galleri testing showing the potential value of adding repeat MCED screening. The timeframe for repeat testing occurred 10-18 months from initial MCED testing.
- Exhibiting 4-year overall survival follow-up demonstrating the prognostic significance of detecting cancer with a methylation-based cfDNA platform like Galleri.
- Illustrating data demonstrating the power of Galleri to preferentially detect high grade, clinically significant prostate cancer over indolent cases.

In the precision oncology setting, GRAIL will discuss the adaptability of its Methylation Platform in identifying cancer histological and molecular subtypes through blood samples.

Oral Presentations

Title: Early Real-World Experience with Repeat Multi-Cancer Early Detection (MCED) Testing
Abstract Number: #3891
Session Category: Clinical Research
Session Title: Application of Real-World Evidence to Cancer Care
Date/Time: Monday, Apr. 8, 2024 from 2:30 PM – 4:30 PM
Location: Room 6 CF – Upper Level – Convention Center

Title: A Targeted Methylation-Based Multi-Cancer Early Detection Blood Test Preferentially Detects High-Grade Prostate Cancer and Minimizes Overdiagnosis
Abstract Number: #1264
Session Category: Prevention / Early Detection / Interception
Session Title: Multi-Cancer Early Detection Testing: Where Are We?
Date/Time: Sunday, Apr. 7, 2024 from 3:00 PM – 5:00 PM
Location: Room 28 – Upper Level – Convention Center

Title: Prognostic Significance of Blood-Based Multi-Cancer Detection in Cell-Free DNA: 4-Year Outcomes Analysis
Abstract Number: #3895
Session Category: Clinical Research
Session Title: Early Detection and Progression Biomarkers
Date/Time: Monday, Apr. 8, 2024 from 2:30 PM – 4:30 PM
Location: Ballroom 6 B – Upper Level – Convention Center

Poster Sessions

Title: PATHFINDER 2: A Prospective Study to Evaluate Safety and Performance of a Multi-Cancer Early Detection Test in a Population Setting
Abstract Number: #4784
Session Category: Prevention / Early Detection / Interception
Session Title: Population-Based Screening
Date/Time: Tuesday, Apr. 9, 2024 from 9:00 AM – 12:30 PM
Location: Poster Section 32

Title: Identification of Cancer Subtypes with a ctDNA-based Targeted Methylation Assay
Abstract Number: #7566
Session Category: Clinical Research
Session Title: Molecular Biology in Clinical Oncology: Characterizing and Modulating Epigenetics and Gene Expression
Date/Time: Wednesday, Apr. 10, 2024 from 9:00 AM – 12:30 PM
Location: Poster Section 43

Title: Most Cancer Deaths are Unaddressed by Current Screening Paradigms
Abstract Number: #6075
Session Category: Prevention / Early Detection / Interception
Session Title: Biomarker-Based Screening
Date/Time: Tuesday, Apr. 9, 2024 from 1:30 PM – 5:00 PM
Location: Poster Section 31

Title: Association of Circulating Free DNA (cfDNA) Maximum Variant Allele Frequency (mVAF) Levels with Clinical Outcomes in Patients (pts) with Metastatic Nonsquamous Non-small Cell Lung Cancer (NSCLC) Treated with Pembrolizumab (pembro) + Chemotherapy (chemo) in the Phase 2 KEYNOTE-782 Trial
Abstract Number: #LB107
Session Category: Clinical Research
Session Title: Late-Breaking Research: Clinical Research 1
Date/Time: Monday, Apr. 8, 2024 from 9:00 AM – 12:30 PM
Location: Poster Section 51

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 new proactive tool to screen for cancer. It is a blood test that can help screen for many of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, and liver.* The Galleri test can identify DNA shed by cancer cells (unique "fingerprints") to screen for some of the deadliest cancers before they become symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test provides direction to doctors on the cancer's origin and helps guide next steps for diagnosis. 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. It is recommended for people over the age of 50, or those with an elevated risk for cancer due to genetics, family history, environmental exposure, or other risk factors.**

For more information, visit galleri.com.

*Editor's note: 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).

** Galleri has not been studied in people under 50 years of age with additional risk factors.

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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