



GRAIL Showcases Methylation Platform Performance Across Cancer Continuum with New Data at American Association for Cancer Research (AACR) Annual Meeting

April 11, 2023

Data Highlight How GRAIL's Targeted Methylation Technology Can Support Detection of Cancer in Pre-Symptomatic to Post-Diagnosis Settings

MENLO PARK, Calif., Apr. 11, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, will present new data showcasing the performance of its methylation platform to detect cancer across the early- and post-diagnosis settings at the American Association for Cancer Research (AACR) Annual Meeting in Orlando, April 14-19, 2023.

"Data at AACR from our clinical development program support the potential of our methylation-based technology platform to transform cancer detection and care for people across all stages of their cancer journey," said Josh Ofman, MD, MSHS, president at GRAIL. "In addition to case studies of our Galleri® multi-cancer early detection test in clinical practice, and demonstrating the unmet need for patients presenting with non-specific symptoms suggestive of cancer, we are excited to share results evaluating the performance of our new research-use only, methylation-based solution for post-diagnosis applications."

In the early-diagnosis setting, GRAIL will present real-world case studies of the Galleri multi-cancer early detection (MCED) test that demonstrate how Galleri led to early detection and treatment of cancer in asymptomatic individuals and directed diagnostic evaluation. In these instances, the Galleri test allowed the cancers to be detected in early stages and before clinical presentation.

In the post-diagnosis setting, analytical validation data will show how GRAIL's targeted methylation technology platform can be used for diagnostic decision support to aid in achieving timely and cost-effective management of patients and after cancer diagnosis. GRAIL will present results from an analytical validation of its research-use only technology solution to accelerate cancer research in the post-diagnosis setting, launched as an offering to biopharmaceutical companies in January 2023. Potential research use cases for the methylation-based solution include, but are not limited to, prognosis, minimal residual disease detection, and recurrence monitoring across different cancer types.

Late-Breaking Poster Sessions

Title: Analytical validation of a tissue-free, multi-cancer, post-diagnosis cancer research test that uses cell-free DNA methylation profiling

Abstract Number: LB297

Session Title: Late-Breaking Research: Clinical Research 3

Date/Time: Wednesday, April 19, 2023, 9 AM – 12:30 PM EST

Location: Section 34

Poster Sessions

Title: A case of stage I HPV-mediated oropharyngeal squamous cell carcinoma (SCC) diagnosed using a multi-cancer early detection (MCED) test

Abstract Number: 6523

Session Title: Early Detection and Molecular Markers of Prevention

Date/Time: Wednesday, April 19, 2023, 9 AM – 12:30 PM EST

Location: Section 28

Title: A case of stage IIA anal squamous cell carcinoma (SCC) diagnosed using a multi-cancer early detection (MCED) test

Abstract Number: 6503

Session Title: Early Detection and Molecular Markers of Prevention

Date/Time: Wednesday, April 19, 2023, 9 AM – 12:30 PM EST

Location: Section 28

Title: Clonal B-cell expansion and the potential challenges to blood-based early cancer detection

Abstract Number: 779

Session Title: Omics and Imaging Approaches in Cancer Risk, Early Detection and Response Assessment

Date/Time: Sunday, April 16, 2023, 1:30 PM – 5 PM EST

Location: Section 28

Title: Patient characteristics, diagnostic journey, and cancer enrichment among pts with nonspecific signs and/or symptoms in the US community oncology setting: a real-world retrospective study

Abstract Number: 6752

Session Title: Retrospective Clinical Analyses 2

Date/Time: Wednesday, April 19, 2023, 9 AM – 12:30 PM EST

Location: Section 42

Title: Utility of ctDNA-based targeted methylation MRD assay for hematological malignancies

Session Title: Liquid Biopsies: Circulating Nucleic Acids and Circulating Tumor Cells 3

Date/Time: Monday, April 17, 2023, 1:30 – 5 PM EST

Location: Section 43

Abstract Number: 3369

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 developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. 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 earlier that cancer is detected, the higher the chance of successful outcomes. The Galleri multi-cancer early detection test can detect a shared cancer signal across more than 50 types of cancer, as defined by the American Joint Committee on Cancer Staging Manual, through a routine blood draw. When a cancer signal is detected, the Galleri test predicts the cancer signal origin, or where the cancer is located in the body, with high accuracy to help guide the next steps to diagnosis. 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 about Galleri, 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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