GRAIL to Present Final Multi-Cancer Early Detection Data from the Interventional PATHFINDER Study at ESMO Congress 2022

September 8, 2022

Final Data From One of the Largest Multi-Cancer Early Detection Studies in an Intended Use Population

MENLO PARK, Calif., Sept. 8, 2022 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, today announced final results from the interventional PATHFINDER study will be presented at the European Society for Medical Oncology (ESMO) Congress 2022 in Paris. PATHFINDER data evaluating the Galleri® multi-cancer early detection (MCED) blood test will be shared in a September 11 proffered paper session. Participant-reported outcomes will also be presented, including satisfaction related to MCED testing, ongoing adherence with standard of care screening, and information related to participants' anxiety and distress. Interim results from the PATHFINDER study were presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

The PATHFINDER single-arm interventional study was designed to evaluate the clinical care pathways following a "cancer signal detected" Galleri test result, measure the time required to achieve diagnostic resolution (primary endpoint), and assess the implementation and performance of Galleri in a clinical care setting.

"Despite 50 years of waging a war on cancer, cancer is poised to become the world's number one killer, in large part because most cancers are diagnosed too late. While current screening tests are saving lives, they are not enough, and the status quo in cancer screening is simply unacceptable. In the United States, we routinely screen for only five cancers yet most cancer deaths occur from cancers we are not looking for. Our current approach using decades old technology with suboptimal adherence is simply not finding enough cancer in the population. We must transition from only looking for individual cancers to also looking at individuals for many cancers," said Josh Ofman, MD, MSHS, president at GRAIL. "We are excited to share the final PATHFINDER results, which provide important insights about the feasibility of our first-of-its-kind MCED technology, the clinical care pathways following a "cancer signal detected" result, and Galleri's potential to detect more cancers in their earlier stages as a complement to standard screenings."

The PATHFINDER study enrolled 6,662 individuals aged 50 years or older, an age group at elevated risk for cancer, but with no suspicion of active cancer. Participants were enrolled across 11 sites, including the Cleveland Clinic, Dana-Farber Cancer Institute, Mayo Clinic, Oregon Health & Science University, Sutter Health and the US Oncology Network. Results will be presented from both an earlier version of Galleri (MCED-E) and a pre-specified retrospective analysis evaluating the current version of the Galleri test (MCED-Scr) using banked blood samples.

Selected GRAIL presentations at ESMO include:

A Prospective Study of a Multi-Cancer Early Detection Blood Test (Presentation #903O)
Session Type: Proffered Paper Session
Date/Time: Sunday, Sept. 11, 16:30 – 16:40 p.m. CEST (10:30 – 10:40 a.m. EST)
Location: 7.3.O – Orleans Auditorium
Speaker: Deborah Schrag, MD, MPH, chair of the Department of Medicine at Memorial Sloan Kettering Cancer Center (MSK)

Evaluation of Anxiety, Distress and Satisfaction With a Multi-Cancer Early Detection Test (Presentation #908P)
Session Type: e-Poster
Date/Time: Sunday, Sept. 11
Speaker: Deborah Schrag, MD, MPH, chair of the Department of Medicine at Memorial Sloan Kettering Cancer Center (MSK)

Time to Diagnosis Among Patients with Cancer in the US (Presentation #1318MO)
Session Type: Mini Oral Session
Date/Time: Monday, Sept. 12, 17:10 – 17:15 CEST (11:10 – 11:15 a.m. EST)
Location: 7.3.M – Marseille Auditorium
Speaker: Matthew Gitlin, PharmD, BluePath Solutions

Abstracts are available on the ESMO Congress 2022 website. Additional data from the PATHFINDER study will be presented at the Congress.

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About GRAIL's MCED Clinical Development Program
The Galleri clinical development program consists of studies that collectively include more than 335,000 participants – and what is believed to be the largest linked datasets of genomic and clinical data in the cancer field. GRAIL's program includes the foundational CCGA development and validation study, the interventional PATHFINDER and PATHFINDER 2 studies, the NHS-Galleri randomized, controlled clinical study, the STRIVE and SUMMIT observational studies, and the REFLECTION real-world registry. The largest of these, the NHS-Galleri trial, has enrolled 140,000 participants with the primary objective of a reduction in late-stage cancer diagnoses, thought to be a necessary prerequisite for a mortality reduction.

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 dated 29 October 2021.

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 signals 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 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 intended for use in people with an elevated risk of cancer, such as those aged 50 or older.

All cells – cancer and healthy ones – shed DNA, which is called cell-free DNA, into the bloodstream. One of the “hallmarks of cancer” is when methyl groups are added to DNA. This does not alter the DNA code but it can alter gene expression. Methylation patterns on tumor-derived cell-free DNA carry cancer-specific signals and are therefore very helpful in detecting cancer and determining its origin. Galleri uses next-generation sequencing and machine learning algorithms to analyze these methylation patterns of cell-free DNA in the bloodstream.

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 “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.

For GRAIL

Corporate Communications
Trish Rowland
Cammy Duong
pr@grail.com

Investor Relations
Alex Dobbin
ir@grail.com