GRAIL Receives New York State Approval for Galleri Multi-Cancer Early Detection Blood Test

September 20, 2021

— Galleri Now Commercially Available to Patients and Healthcare Providers in the Empire State —

MENLO PARK, Calif., September 20, 2021 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early, today announced that the New York State Department of Health (NYSDOH) has approved Galleri™, GRAIL's groundbreaking multi-cancer early detection blood test. With NYSDOH approval, Galleri is now available to residents in the state of New York by prescription to complement existing single cancer screening tests.

The standard set by New York State represents one of the most rigorous levels of validation required for laboratory developed tests. Clinical laboratories conducting testing on specimens from New York residents also must obtain a clinical laboratory permit. The permit of a clinical laboratory helps ensure the accuracy and reliability of clinical tests.

"We are pleased that healthcare providers in New York can now prescribe Galleri, a first-of-kind blood test that can detect multiple cancers early, when treatment is more likely to be successful," said Dr. Josh Ofman, chief medical officer and head of external affairs at GRAIL. "The approval of the New York State Department of Health marks a significant regulatory milestone for GRAIL and confirms the high standard for validation of our rigorous approach to test development, and the high quality of our clinical laboratory. Most importantly, this approval represents a significant milestone in bringing Galleri to patients and healthcare providers across the U.S., and continued progress toward our mission to detect cancer early, when it can be cured."

The GRAIL laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) and accredited by the College of American Pathologists (CAP). Widely recognized as a gold standard for clinical laboratory accreditations, the CAP Laboratory Accreditation Program is designed to ensure laboratories meet stringent requirements and standards of quality, safety, and accuracy.

More than 600,000 people died from cancer last year in the U.S., according to the American Cancer Society. This is in large part because the majority of cancers are found too late when outcomes are often poor. Recommended screening tests save lives, but only cover five cancer types in the U.S.: breast, colon, cervical, prostate, and in high-risk smokers, lung. In fact, 71% of cancer deaths have no recommended early detection screening at all.

About Galleri

The earlier that cancer is detected, the higher the chance of successful outcomes. The Galleri multi-cancer early detection test can detect more than 50 types of cancer 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.

For more information about Galleri, visit www.galleri.com.

About GRAIL

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on saving lives and improving health by pioneering new technologies for early cancer detection. 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 overcome one of medicine's greatest challenges with Galleri, GRAIL's multi-cancer early detection blood test. With this proprietary technology, GRAIL is also developing solutions to help accelerate cancer diagnoses, blood-based detection for minimal residual disease, and other post-diagnostic applications. GRAIL, a wholly-owned subsidiary of Illumina, Inc., is headquartered in Menlo Park, California, with locations in Washington, D.C., North Carolina, and the United Kingdom.

Important Safety Information

Galleri 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.

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. Galleri is prescription 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 (CAP). 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.

Contacts

For GRAIL:

Corporate Communications
Kelsey Grossman
pr@grail.com

Investor Relations
John Craighead
ir@grail.com