GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test

June 4, 2021

— Galleri's ability to detect more than 50 types of cancer with a single blood draw could transform early cancer detection as a complement to existing screenings; test now available in U.S. by prescription only —

MENLO PARK, Calif., June 4, 2021 — GRAIL, Inc., a healthcare company whose mission is to detect cancer early, today presented the first results from the interventional PATHFINDER study evaluating Galleri™, a multi-cancer early detection (MCED) blood test. The results, presented at the 2021 ASCO Annual Meeting, support Galleri's performance in clinical settings. The company also announced today that Galleri is now available in the U.S. by prescription only.

"The interim results of PATHFINDER demonstrate that a routine blood test is capable of detecting many different cancers even before symptoms arise, an approach that has significant potential advantages," said Dr. Tomasz M. Beer, deputy director at the OHSU Knight Cancer Institute and presenting author. "Most importantly, it can detect cancers that have no recommended screening tests today, and more than two-thirds of cancers go unscreened for this reason. These results are a pivotal step toward extending early detection to many more types of cancer."

Clinical Data from PATHFINDER

PATHFINDER was designed to assess the implementation and performance of Galleri in a clinical care setting, evaluate the clinical care pathways following a "signal detected" Galleri test result, and measure the time required to achieve diagnostic resolution.

The study analyzed 6,629 individuals aged 50 years or older, an age group at elevated risk for cancer, but with no suspicion of active cancer. Compared to the general population, participants had equal or higher compliance with recommended breast and colon cancer screening tests.

In the interim analysis, an earlier version of Galleri accurately detected 29 cancers across 13 types: breast, colon or rectum, head and neck, liver and bile duct, lung, lymphoid leukemia, lymphoma, ovary, pancreas, plasma cell neoplasm, prostate, small intestine, and Waldenstrom macroglobulinemia. Of the new cancers detected, nearly 40% (9/23) were localized (stage I-II), and more than half (13/23) were detected before distant metastases (stage I-III). PATHFINDER participants will continue to be followed for 12 months, with final results expected in the first half of 2022.

"Finding cancer early, when treatment is more likely to be successful, is one of the most significant opportunities we have to reduce the burden of cancer," said Dr. Joshua Ofman, chief medical officer and head of external affairs at GRAIL. "These data suggest that, if used at scale alongside existing screening tests, the Galleri test could have a profound impact on how cancer is detected and, ultimately, on public health."

The interim PATHFINDER positive predictive value (PPV), or the likelihood that a person has cancer when a positive test result is returned, was 44.6% (95% CI: 33.2-56.7%), which is consistent with findings from GRAIL's case-controlled Circulating Cell-free Genome Atlas (CCGA) Study.

When cancer was confirmed, Galleri's first or second cancer signal origin prediction was 96.3% accurate (95% CI: 81.7-99.8%), with a median observed time to cancer diagnosis of 50 days. The interim analysis identified only four study-related adverse events (two related to mild anxiety before the test, one related to mild anxiety about the blood draw, and one related to mild bruising).

"Early cancer detection is critical to reducing the burden of cancer-related morbidity and mortality. These results reflect the potential real-world ability of Galleri to find deadly cancers earlier, and represent a leap forward in the effort to treat cancer more effectively," Dr. Beer said.

Data is presented by Dr. Beer, and the presentation will be available at https://grail.com/presentations.

Introducing Galleri

Galleri is now available in the U.S. by prescription only. The Galleri test is intended for use in those with an elevated risk of cancer, such as adults aged 50 or older, and as a complement to existing single cancer screening tests.

In an observational study, Galleri has demonstrated the ability to detect more than 50 types of cancer, over 45 of which lack recommended screening tests today in the U.S., with a low false positive rate of less than 1%. When cancer is detected, Galleri can determine the cancer signal origin with high accuracy. New CCGA data published today in *Clinical Cancer Research*, a journal of the American Association for Cancer Research, also demonstrate the ability of GRAIL's technology to preferentially detect cancers that are more aggressive than expected based on age, and the cancer stage and type.

The blood test is supported by what is believed to be the largest clinical study program in genomic medicine, with over 140 clinical study sites, including the Mayo Clinic, Dana-Farber Cancer Institute, Cleveland Clinic, Sutter Health, OHSU, Intermountain Healthcare, and U.S. Oncology Research.

Cancer is expected to become the leading cause of death in the United States this year, in large part because the majority of cancers are found too late when outcomes are poor. Recommended screening tests save lives, but only cover five cancer types in the U.S. In fact, 71% of cancer deaths in the U.S. have no recommended early detection screening.

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

REFLECTION Registry

GRAIL also announced it will establish a real-world evidence study, REFLECTION, to understand the experience and clinical outcomes of 35,000

individuals in the U.S. who are prescribed the Galleri test from a healthcare provider. This follows an announcement last fall that Galleri will be offered to eligible patients in the United Kingdom (UK) later this year as part of a partnership with the UK National Health Service to support its Long Term Plan for earlier cancer diagnoses.

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.

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 is headquartered in Menlo Park, California, with locations in Washington, D.C., North Carolina, and the United Kingdom. It is supported by leading global investors and pharmaceutical, technology, and healthcare companies.

Contact

Corporate Communications
Kelsey Grossman
pr@grail.com

Investor Relations
John Craighead, Ph.D.
ir@grail.com