GRAIL To Initiate REACH Study To Evaluate Clinical Impact Of Galleri® Multi-Cancer Early Detection (MCED) Test Among The Medicare Population

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Prospective, Multi-Center Study Will Assess the Clinical Impact of Galleri® in addition to Currently Recommended Cancer Screenings in the Medicare Population

REACH Recruitment Will Include a Focus on Individuals From Historically Under-Represented Groups

Costs of Galleri and Related Items and Services for Study Participants Will be Covered by Medicare

MENLO PARK, Calif., Nov. 20, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, today announced that it will initiate **R**eal-world **E**vidence to **A**dvance Multi-**C**ancer Early Detection **H**ealth Equity (REACH/Galleri-Medicare study) following the U.S. Food and Drug Administration's (FDA) approval of GRAIL's Investigational Device Exemption (IDE) application and the Centers for Medicare and Medicaid Services' (CMS) approval for Medicare coverage of the study. With age being the most significant risk factor for cancer, Medicare beneficiaries face the highest unmet need for early cancer detection.

The Galleri-Medicare study is a first-of-its-kind real-world study designed to further evaluate the clinical impact of the Galleri® multi-cancer early detection (MCED) test among Medicare beneficiaries, including racial and ethnic minorities, and seniors from historically under-served communities. The Galleri-Medicare study seeks to compare up to 50,000 Medicare beneficiaries who have received usual care plus an annual Galleri test with a matched comparator arm of beneficiaries who receive usual care alone. Medicare will cover the costs of Galleri and related and routine items and services for study participants.

"Although recommended cancer screening tests save lives, they are only available in the U.S. for three types of cancers for women, and two types for men, with an additional screening for those with a heavy smoking history. Multi-cancer early detection holds the promise to detect more cancers earlier, improve cancer outcomes, and reduce overall cancer costs, but only if accessible to all seniors," said Bob Ragusa, chief executive officer at GRAIL. "The Galleri-Medicare study demonstrates our commitment to provide broad, equitable access to early cancer detection that is representative of the U.S. population, including groups that are often under-represented in clinical research. GRAIL designed the Galleri-Medicare study to meet the aspirations of the Cancer Moonshot's goal of advancing early detection, add to our robust ongoing real-world evidence generation, and continue to demonstrate Galleri's clinical benefit for early detection."

More than 600,000 people died from cancer last year in the United States with over 400,000 of those deaths among people age 65 and older. More than half of all cancer diagnoses are among Medicare beneficiaries who are at the highest risk for cancer due to age. This is largely because the majority of cancers that result in death are found too late when outcomes are often poor. In fact, about seven in 10 cancer deaths are from cancers that lack recommended early detection screening.

"New approaches to screening for cancers hold the potential to transform oncology research and care, and most importantly, improve patient outcomes," said Jeff Allen, President & CEO of Friends of Cancer Research, "This new real-world evidence program will augment the ongoing randomized clinical trial and generate the necessary clinical impact data to optimize the use of multi-cancer early detection testing in the broad population."

Racial and ethnic minorities continue to bear a higher cancer burden, and late-stage diagnosis of unscreened cancers remains disproportionately higher among Black and Brown communities, according to the National Minority Quality Forum. The Galleri-Medicare study will seek to include Medicare participants from under-represented populations across race, ethnicity, socioeconomic status and underserved communities.

Garfield A.D. Clunie, MD, the 123rd president of the National Medical Association (NMA), the nation's oldest and largest association of African American/Black physicians said, "The National Medical Association (NMA) is the nation's leading voice for advocacy for health equity and the elimination of health disparities. NMA uniquely understands that equitable access to early cancer detection has the potential to achieve better outcomes in diverse populations with a potential to combat barriers to care such as access and reduction of stigma that present challenges. The NMA asserts that earlier diagnosis can only be achieved if all patients have broad access to MCED tests. This innovative study will help provide access to game-changing cancer detection technology for our nation's seniors and we applaud the added outreach efforts to engage those who are minority and underrepresented populations in underserved areas to further add to the growing body of representative real-world evidence."

In addition to the robust clinical evidence collection from GRAIL's IDE-approved studies – such as the NHS-Galleri trial and the US PATHFINDER 2 trial – the Galleri-Medicare study will generate large-scale real-world evidence of Galleri performance and outcomes in the diverse Medicare population. The clinical impact measures of interest in the study include reduction in diagnosed stage IV cancers, safety, and healthcare resource utilization associated with diagnostic workup for suspected cancer within the interventional arm compared to usual care. While study timelines are still under development, it is anticipated that interim study data will be available for CMS consideration in the event of FDA approval of a premarket approval application (PMA) for Galleri.

"At the heart of our work at GRAIL is the unique ability to generate large-scale evidence of Galleri's clinical impact that supports broad, equitable access from multiple studies and hundreds of thousands of individuals, including diverse populations, and population-scale partnerships with dozens of major health care institutions in the U.S. and in England's National Health Service. We expect that the data collected from the Galleri-Medicare study will add to the growing body of evidence that MCED has the potential to change the future of cancer detection as we know it," said Josh Ofman, MD, MSHS, President at GRAIL. "To bend the cancer mortality curve downwards, we have to shift from only screening for a few individual cancers to also screening individuals for many cancers lacking screening, which we believe will lead to better outcomes and lower diagnosis and treatment costs."

This growing body of evidence includes the final results of GRAIL's prospective PATHFINDER study that were recently published in *The Lancet*,

demonstrating that adding MCED screening to standard of care screening more than doubled the number of cancers detected compared with standard of care screening alone. Most of the cancers found had no recommended screening options, and nearly half detected were in their early stages. At ASCO 2023, GRAIL presented new data demonstrating that the real-world performance of MCED is generally consistent to that seen in PATHFINDER. Additionally, in partnership with England's National Health Service, NHS-Galleri is an ongoing randomized controlled trial of more than 140,000 participants with the primary objective of reducing late-stage cancer diagnoses, in line with the UK's overarching goal of finding cancer early for its population. In addition, to date, more than 100,000 commercial Galleri tests have been processed.

Please view this video that provides an overview of the REACH study.

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.

Important Information About the REACH Study
The REACH Study is sponsored by GRAIL and will enroll approximately 50,000 participants across several health systems. The REACH Study is being conducted under FDA's approval of an IDE application. More information about the REACH Study will be available on clinicaltrials.gov.

Galleri is a blood-based multi-cancer early detection (MCED) test. In prior clinical studies, Galleri has shown the ability to detect a signal shared by more than 50 types of cancer through a routine blood draw. If a cancer signal is detected, the Galleri test predicts the location or origin of the cancer.

In the REACH Study, the Galleri test is an investigational test with associated risks and benefits that are described in the study materials. Risks of the test include, but are not limited to,false-positive results (a cancer signal detected when cancer is not present), false-negative results (no cancer signal detected when cancer is present), and incorrect prediction of the location or origin of a cancer signal. The Galleri test should not replace any guideline-recommended screenings or other standard of care diagnostic or treatment options.

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. 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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