



GRAIL Confirms Q2 2021 Introduction of Galleri, First-of-Kind Multi-Cancer Early Detection Blood Test

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— PATHFINDER Study Enrollment Completed, Results Expected to Support Galleri Launch —

MENLO PARK, Calif., January 11, 2021 – GRAIL, Inc., a healthcare company whose mission is to detect cancer early, when it can be cured, today confirmed it expects to introduce Galleri™, its multi-cancer early detection blood test, in the second quarter of 2021.

In December, GRAIL completed the enrollment of PATHFINDER, a prospective, 6,600-participant multi-site interventional study conducted under a U.S. Food and Drug Administration Investigational Device Exemption application to evaluate the implementation of Galleri in clinical practice. PATHFINDER has completed its second planned independent Data and Safety Monitoring Board review. Presentation of initial results from PATHFINDER, and additional clinical validation data from GRAIL's foundational Circulating Cell-free Genome Atlas (CCGA) study, are expected in the first half of 2021. Together, these data are expected to support Galleri's introduction as a laboratory developed test (LDT).

"Cancer remains the second-leading cause of death in large part because we lack recommended screening tests for the majority of deadly cancers. We are excited by the progress made in our mission to detect cancer earlier and what's to come with the introduction of Galleri this year," said Hans Bishop, chief executive officer at GRAIL. "We are encouraged by the significant early interest in Galleri from health systems, medical practices, and self-insured employers."

GRAIL is conducting what it believes is one of the largest clinical study programs of its kind, with more than 134,000 participants enrolled to date. An earlier version of Galleri demonstrated the ability to detect more than 50 types of cancers — over 45 of which lack recommended screening tests today — with a low false positive rate of less than 1%. When a cancer signal is detected, Galleri can determine where in the body the cancer is located with high accuracy, all from a single blood draw.

Galleri is available under investigational use in PATHFINDER, where it is being used to guide clinical care. Galleri is also expected to be offered to eligible patients in the United Kingdom (UK) starting in 2021 as part of a partnership with the UK National Health Service to support its Long Term Plan for earlier cancer diagnoses in an effort to transform cancer outcomes.

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 test. An earlier version of Galleri demonstrated the ability to detect more than 50 types of cancers — over 45 of which lack recommended screening tests today in the U.S. — with a low false positive rate of less than 1%. 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.

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