GRAIL Submits FDA Premarket Approval Application for the Galleri® Multi-Cancer Early Detection Test

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FDA Submission Marks a Pivotal Milestone in Advancing Early Cancer Detection, Addressing Unmet Needs in Cancer Screening

MENLO PARK, Calif., Jan. 29, 2026 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced the submission of the final module of the Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for its Galleri® multi-cancer early detection (MCED) test. The FDA designated the test as a Breakthrough Device in 2018.

"Cancer is now the leading killer of adults over 50 years old in the U.S., and most deadly cancers are often discovered too late, when they are difficult to treat and typically have worse outcomes," said Josh Ofman, MD, MSHS, President at GRAIL. "There is nothing acceptable about the status quo in cancer screening. Adding Galleri to standard-of-care single cancer screening tests has the potential to dramatically improve the performance of the nation's current screening program and expand opportunities for earlier treatment and improved outcomes. Galleri has been rigorously studied in case-controlled and interventional studies. This FDA submission marks a critical step toward making Galleri available to more people and advancing early detection to provide a significant public health benefit."

The PMA submission is focused on the test performance and safety results from 25,490 consented participants in the US-based PATHFINDER 2 study with one year of follow up and from the prevalent screening round (first year) of the NHS-Galleri trial, the largest, and only, randomized, controlled trial of any MCED test in an intended use population. The submission is also supported by a bridging analysis to compare performance of the version of Galleri used in the PATHFINDER 2 study and the NHS-Galleri trial to the updated PMA version that has been submitted to the FDA for premarket approval.

About the NHS-Galleri trial (NCT05611632)
The NHS-Galleri trial is the first and only prospective, randomized, controlled trial to assess the clinical utility and performance of a multi-cancer early detection test for population screening when added to standard care. The trial recruited more than 140,000 asymptomatic participants, aged 50 to 77, and was conducted in partnership with the NHS in England. Participants provided three blood samples over two years, about 12 months apart. The primary objective of the NHS-Galleri trial is to show a reduction in late-stage (III-IV) cancers in people who received the Galleri test compared with those who did not. This will be measured in three clinically important groups of cancers, focusing first in a pre-specified group of 12 cancer types that together represent approximately two-thirds of cancer deaths in England and the United States. Secondary objectives include reduction in stage IV cancer; performance of the Galleri test, including positive predictive value and false positive rate; cancer detection rate; safety; and healthcare resource utilization.

About the PATHFINDER 2 Study (NCT05155605)
PATHFINDER 2 is a prospective, multi-center, interventional study evaluating the safety and performance of Galleri in approximately 35,000 individuals aged 50 years and older who are eligible for guideline-recommended cancer screening in the United States. The primary objectives of the study are 1) to evaluate the safety and performance of the Galleri MCED test based on the number and type of diagnostic evaluations performed in participants who receive a cancer signal detected test result, and 2) to evaluate the performance of the Galleri MCED test across various measures, including PPV, negative predictive value (NPV), sensitivity, specificity, and CSO prediction accuracy. Participants who receive a cancer signal detected result undergo additional diagnostic testing based on the predicted CSO to determine if a cancer is present. Secondary objectives include utilization of guideline-recommended cancer screening procedures after use of the MCED test, and participant reported outcomes over several time points, including an assessment of participants' anxiety and satisfaction with the MCED test.

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.
For more information, visit grail.com.

Forward Looking Statements
This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would," or "will," the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about GRAIL, Inc. (the "Company"), include the benefits and use of the Galleri test, the potential of the Galleri MCED test, including its benefits alongside standard of care screening, upcoming events and presentations, the sufficiency of the PMA submission package, including the results of the NHS-Galleri, PATHFINDER 2 and bridging analysis, for approval by the FDA, potential labeling in any approved PMA, planned commercial use of the PMA version of Galleri, if and when approved, and the timeline for review and approval of the PMA submission by the FDA.

These statements are only predictions based on the Company's current expectations and projections about future events and trends. There are important factors that could cause actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors and numerous associated risks discussed under the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the period ended December 31, 2024 and Quarterly Reports on Form 10-Q for the periods ended March 31, 2025, June 30, 2025 and September 30, 2025. Moreover, the Company operates in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for the Company's management to predict all risks, nor can the Company assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of the Company's control. Although the Company believes the expectations and projections expressed or implied by the forward-looking statements are reasonable, it cannot guarantee future results, level of activity, performance, or achievements. Actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, the Company undertakes no obligation to update any of these forward-looking statements after the date of this press release to conform prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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