GRAIL Announces FDA Advisory Committee Meeting to Review Premarket Approval Application for the Galleri® Multi-Cancer Early Detection Test

August 7, 2026

MENLO PARK, Calif., Aug. 7, 2026 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced that the U.S. Food and Drug Administration's (FDA) Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee is scheduled to meet on Sept. 23, 2026 to review the Premarket Approval (PMA) application for the Galleri® multi-cancer early detection (MCED) blood test.

The Galleri test is designed to detect cancer-specific methylation patterns shared by many types of cancer before symptoms appear, including cancers that do not have recommended screening today. When a cancer signal is detected, Galleri is designed to predict the cancer signal origin with high accuracy to help guide diagnostic evaluation. The test is intended to be used in addition to, and not as a replacement for, guideline-recommended screenings.

"Today, the status quo in cancer screening is simply unacceptable. Many cancers are detected too late, after symptoms appear and the disease is too advanced for effective or curative-intent treatments. In fact, 70-80% of cancer deaths occur due to cancers we are not screening for at all. GRAIL has pioneered a breakthrough technology, the Galleri test, designed to transform cancer screening by detecting more cancers before symptoms appear, including many of the deadly cancers that lack recommended screenings today. The Galleri technology is unique in how it is designed to examine the methylome using proprietary technology and artificial intelligence. We have generated extensive data in multiple studies to evaluate the impact of adding Galleri to standard of care screening with positive results showing evidence of increases in screen detected cancers, a low false positive rate and high signal origin prediction accuracy. Adding Galleri to recommended screening could result in a more effective and efficient cancer screening program in the U.S.," said Josh Ofman, MD, MSHS, CEO at GRAIL. "Galleri is the only MCED test supported by large interventional and randomized, controlled studies in intended use populations. We appreciate the FDA's leadership in advancing the review of the first premarket approval application for an MCED, and we look forward to discussing Galleri's clinical data and the opportunity for multi-cancer early detection to address a significant unmet public health need, with the Advisory Committee."

GRAIL submitted its PMA application for Galleri to the FDA on Jan. 29, 2026. The FDA designated Galleri as a Breakthrough Device in 2018. The PMA submission is focused on the test performance and safety results from 25,490 consented participants with one year of follow up in the US-based PATHFINDER 2 study as well as data from over 70,000 participants from the intervention arm of the prevalent screening round (first year) of the NHS-Galleri trial, the largest and only randomized, controlled trial of an MCED test in an intended use population. The submission is also supported by an 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 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. GRAIL is headquartered in Menlo Park, Calif. with locations in Washington, D.C., North Carolina, and the United Kingdom.

For more information, visit grail.com.

GRAIL 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 us, may include statements related to the potential benefits, uses and impacts of the Galleri test, extrapolation of trends in the results, comparability of the results to a real world setting, benefits of population screening with Galleri, the applicability of the clinical study results to the commercial or FDA versions of the Galleri test and expectations regarding the advisory committee presentation, discussion and outcomes, including the expected date of such meeting, among others.

These statements are only predictions based on our current expectations and projections about future events and trends. There are important factors that could cause our 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 our Annual Report on Form 10-K for the period ended December 31, 2025 and our subsequent Quarterly Reports on Form 10-Q. Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our 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 we may make.

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 our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results, financial condition and success in our business strategies and operations may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this press release to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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