FDA Advisory Committee Votes In Favor of Approval of GRAIL's Galleri® Multi-Cancer Early Detection Test

September 23, 2026

SUNNYVALE, Calif., Sept. 23, 2026 /PRNewswire/ -- GRAIL, Inc., a healthcare company whose mission is to detect cancer early when it can be cured, today announced a favorable vote from the Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee (the Committee) of the U.S. Food and Drug Administration (FDA) for the approval of the Premarket Approval (PMA) application of the Galleri® multi-cancer early detection test (MCED).

In three separate votes, the 10 voting members of the Committee considered Galleri's safety, effectiveness and overall benefit-risk profile for screening for the early detection of multiple types of cancer in adults aged 50 years and older. The Committee voted seven to two with one abstention that the benefits of Galleri outweigh its risks, unanimously in support of Galleri's safety, and six to four in support of Galleri's effectiveness.

"The Galleri test was developed to improve the effectiveness and efficiency of our national cancer screening program by adding multi-cancer early detection to recommended screening—helping find more cancers safely, when they may be easier and less costly to treat, and it still may be possible for a patient to receive treatment with curative intent," said Josh Ofman, MD, MSHS, CEO at GRAIL. "Today's vote reinforces the strength of Galleri's clinical evidence. We believe the panel's recommendations reaffirm a high evidence bar that GRAIL has set for a multi-cancer early detection test. GRAIL is committed to working with the FDA as it completes its review of Galleri, the first PMA submission for a multi-cancer early detection 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.

"We are heartened by the more than 200 physicians, nurses, professional societies, patients, patient advocates, and others who shared their support for Galleri through the written public docket and open comment period during the panel," said Ofman. "Their voices reflect the real-world urgency of finding more cancers, when outcomes can be improved."

Galleri is the only MCED test supported by large interventional and randomized controlled studies in intended-use populations, including FDA-approved Investigational Device Exemption studies (IDEs), namely PATHFINDER 2 in North America and the landmark NHS-Galleri trial in England. GRAIL's clinical development program is one of the largest in cancer screening with participants across multiple large-scale prospective studies. In clinical studies, Galleri has detected approximately four to seven times more cancers compared to standard of care alone, with most Galleri-detected cancers found at earlier stages, when treatment with curative intent may be possible, while maintaining a low false-positive rate and high Cancer Signal Origin prediction accuracy.

The FDA designated Galleri as a Breakthrough Device in 2018. GRAIL submitted its PMA application for Galleri to the FDA on Jan. 29, 2026.

The FDA convenes advisory committees to obtain independent expert advice. The agency is not bound by the Committee's recommendations, though it takes them into consideration when making final regulatory decisions. The FDA is expected to make a final decision on the Galleri PMA in the coming months.

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 Sunnyvale, 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, the potential benefits of the Galleri test as voted on by the Committee, GRAIL's commitment to continue working with the FDA as the agency completes its review of the Galleri PMA, and the potential impact of the Committee's recommendation on the FDA's final regulatory decision on the Galleri PMA or other MCED tests, including the expected timing of the FDA's final regulatory decision on the Galleri PMA, 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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