



GRAIL Presents New Data Demonstrating That Methylation Assay Detects Residual Hematologic Cancer After Treatment at American Association for Cancer Research Annual Meeting 2023

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GRAIL's Methylation Assay Had 92% Cancer Detection Rate Across Six Hematologic Malignancies With 96% Accuracy in Determining the Hematologic Malignancy Subtype

Findings Support Use of GRAIL's Methylation Platform to Identify Residual Disease in Post-Treatment Settings

MENLO PARK, Calif., and CAMBRIDGE, UK, April 17, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, and AstraZeneca (LSE/STO/Nasdaq: AZN), today presented new data from a study assessing the feasibility of a pan-hematologic malignancy classifier (pan-heme classifier) based on GRAIL's methylation platform as a potential tumor-agnostic, plasma-based cell free DNA minimal residual disease (MRD) test. The study showed that GRAIL's methylation technology had a cancer detection rate of 92% in patients with relapsed or refractory disease across six hematological malignancies. The findings were reported during a poster session at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, held April 14-19.

"Currently there is no standard method to detect residual cancer DNA in patients across multiple types of blood cancer. Following treatment, a small number of cancer cells can remain in the body, which don't cause symptoms but could begin to multiply and cause relapse," said Jeffrey Venstrom, M.D., Chief Medical Officer at GRAIL. "A blood-based methylation test offers a potential solution to evaluate patients periodically with the goal of extending remission and survival."

Baseline blood samples were collected from patients with six subtypes of hematologic malignancies and tested with GRAIL's assay to identify residual cancer using targeted methylation sequencing and advanced machine learning algorithms. The majority of samples (88%) were from relapsed or refractory blood cancers that were blindly tested retrospectively. The pan-heme classifier accurately detected cancer in 92% of the 428 samples tested (98% in chronic lymphocytic leukemia; >98% in multiple myeloma; >95% in non-Hodgkin lymphomas, including diffuse large B-cell lymphoma, follicular lymphoma and mantle cell lymphoma; and 87% in acute myeloid leukemia samples). Cancer was reproducibly detected in 89% (48 of 54) of cases where paired samples were taken prior to treatment, demonstrating high biological precision. Furthermore, serially diluted DLBCL and CLL patient plasma samples were spiked into healthy volunteer plasma samples to estimate an initial pan-heme classifier LOD of 10⁻³ – 10⁻⁴ methyl variant allele fraction (MVAF) with <2% false positive rate. The assay and pan-heme classifier is currently under improvement and optimization.

"The findings presented at AACR support further development of a methylation-based pan-hematologic malignancy algorithm, which could help in standardizing a method of detecting residual cancer DNA in patients after they are treated for various types of blood cancers," said Daniel Auclair, Hematology R&D at AstraZeneca. "These data show that methylated DNA might be a good marker for detecting residual cancer across multiple hematological malignancies in post-treatment settings and warrants further study."

GRAIL previously [announced](#) a broad strategic collaboration with AstraZeneca to develop and commercialize companion diagnostic (CDx) assays for use with AstraZeneca's therapies. The collaboration initially focused on developing companion diagnostic tests to identify patients with high-risk, early-stage disease.

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 developing pioneering technology to detect and identify multiple deadly cancer types early. 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 enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. 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.

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