FDA Grants Breakthrough Device Designation to Freenome's Blood-Based SimpleScreen™ Lung Cancer Screening Test

August 12, 2026

Investigational AI-powered multiomic test is being developed for adults ages 50-80 at high risk who are not currently participating in guideline-recommended lung cancer screening

BRISBANE, Calif., Aug. 12, 2026 (GLOBE NEWSWIRE) -- Freenome, Inc. (Nasdaq: FRNM), an early cancer detection company developing blood-based screening tests, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to SimpleScreen™ Lung, the company's investigational lung cancer screening test.

The designation applies to the proposed use of SimpleScreen Lung in adults ages 50 to 80 who have at least a 20 pack-year smoking history and are not currently participating in guideline-recommended lung cancer screening. The test, which would be ordered by a healthcare provider, is designed to detect early signals of lung cancer in a blood sample from a standard blood draw.

The FDA Breakthrough Devices Program is intended to accelerate the development and review of medical devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases and meet other criteria. The program offers Freenome the opportunity for interactive communication and prioritized review during the premarket submission process.

Lung cancer is the leading cause of cancer death in the United States,[1] yet the screening gap remains substantial. According to the Centers for Disease Control and Prevention, only about 18% of U.S. adults for whom lung cancer screening is recommended have been screened. Today, low-dose computed tomography (LDCT) is the only guideline-recommended screening for lung cancer. Common barriers to LDCT adoption include strict eligibility criteria, lack of awareness, social stigma around smoking, fear of a cancer diagnosis, concern of repetitive radiation exposure, and logistical and financial obstacles.

By offering a non-invasive blood test, Freenome aims to help patients and providers overcome some of those obstacles and make lung cancer screening easier and more accessible.

"The Breakthrough Device Designation from the FDA recognizes the substantial unmet need for lung cancer screening and accelerates our path to bring SimpleScreen Lung to patients," said Aaron Elliott, Ph.D., CEO of Freenome. "By identifying high-risk individuals who would benefit from LDCT, we believe our test will complement the current standard of care and improve detection rates. We continue to advance the clinical work necessary to submit SimpleScreen Lung for FDA review."

The development of SimpleScreen Lung builds upon Freenome's base-level methylation and next-generation sequencing platform, which is the technology underlying the FDA approval last month of the SimpleScreen CRC colorectal cancer screening test. SimpleScreen Lung incorporates multiomics through methylation and proteomics technologies with an AI/ML-powered classifier to determine whether a lung cancer signal has been detected. Under the proposed indication, a positive result means the test detected a signal that may suggest lung cancer and should be followed by LDCT imaging. A negative result means the test did not detect a lung cancer-associated signal, but it does not guarantee the absence of lung cancer. Healthcare providers should determine appropriate follow-up for each individual.

Freenome reported initial development data for the investigational SimpleScreen Lung test at the 2026 AACR Annual Meeting.[2] Freenome is continuing clinical evaluation of the test, including through its prospective PROACT LUNG study (NCT06122077).

About Freenome

Freenome is an early cancer detection company developing blood-based screening tests to identify cancer in its earliest, most treatable stages. The company's proprietary multiomics discovery platform analyzes circulating cell-free DNA methylation patterns at single-base resolution alongside additional biomarkers to detect multiple cancers. Freenome's development of SimpleScreen™ CRC for colorectal cancer screening and a pipeline of tests for lung cancer and additional indications is designed to increase cancer detection among millions of at-risk individuals. For more information, visit www.freenome.com.

Forward-Looking Statements

Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will" and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are making this statement for purposes of complying with those safe harbor provisions. Any statements in this press release that are not statements of historical fact may be deemed to be forward-

looking statements. These forward-looking statements include, without limitation, express or implied statements regarding the Breakthrough Device Designation of SimpleScreen Lung, potential benefits resulting from such designation and related implications including interactions with the FDA and related timing; SimpleScreen Lung's impact and ability to reach additional patients; our plans with respect to the continued development of SimpleScreen Lung and expectations regarding submission to FDA. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks related to the approval of Freenome's products and tests and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive products and tests; ability to obtain sufficient supply of materials; ability to obtain additional financing; ability to attract and retain qualified personnel; global economic and political conditions; legal and regulatory changes; the outcome of any legal proceedings that may be instituted against Freenome; the effects of competition on Freenome's future business; as well as those set forth in the Form S-4 that was filed with the SEC, as updated by our subsequently filed SEC filings. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

References

1. Siegel RL, Kratzer TB, Wagle NS, Sung H, Jemal A. Cancer statistics, 2026. CA Cancer J Clin. 2026;76(1):e70043. doi:10.3322/caac.70043.
2. Cancer Res (2026) 86 (7_Supplement): 1107. https://doi.org/10.1158/1538-7445.AM2026-1107.

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