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Cancer Genetics Receives New York State Approval for FDA-Approved Oncomine Dx Target Test by Thermo Fisher Scientific

The test serves as a companion diagnostic for three targeted therapies in non-small cell lung cancer (NSCLC)

Global NSCLC diagnostic market projected to reach $3.65 billion by 2024

RUTHERFORD, N.J., Dec. 19, 2017 (GLOBE NEWSWIRE) -- Cancer Genetics, Inc. (Nasdaq:CGIX), a leader in enabling precision medicine for oncology through molecular markers and diagnostics, today announced it has received approval for Thermo Fisher Scientific's Oncomine Dx Target Test from the New York State Department of Health. The first FDA-approved test of its kind, the Oncomine Dx Target Test is playing an increasingly important role in lung cancer diagnostics, a market that is projected to reach $3.65 billion by 2024[i].

The Oncomine Dx Target Test is a next-generation sequencing (NGS)-based companion diagnostic (CDx) that simultaneously screens tumor samples for multiple biomarkers associated with three FDA-approved therapies for non-small cell lung cancer (NSCLC), including the combined therapy of dabrafenib and trametinib, crizotinib, or gefitinib.

"We applaud CGI's focused efforts in making available and now gaining approval from the New York State Department of Health for Oncomine Dx Target Test," said Joydeep Goswami, president of Clinical Next-Generation Sequencing and Oncology for Thermo Fisher Scientific.

CGI was one of the first laboratories in the country to make the novel 23-gene test available to the medical community. The Oncomine Dx Target Test helps physicians match patients to targeted therapies in days rather than weeks, eliminating the need for a time-consuming, sequential single-biomarker testing approach.

At CGI, a report for the Oncomine Dx Target Test is ready in five to seven days using as little as 10 nanograms of DNA and RNA from formalin-fixed, paraffin-embedded (FFPE) tissue. This is a critical advantage of the test, given that NSCLC patient samples are often limited in quantity.

The test report not only indicates whether patients have ROS1, EGFR, and BRAF alterations linked to the three FDA-approved treatments (crizotinib, gefitinib, dabrafenib and trametinib, respectively), but also the presence or absence of gene variants in 20 other NSCLC-associated genes.

"CGI was one of the first laboratories and precision medicine companies in the country to offer the Oncomine Dx Target Test, and now it is the first and only laboratory to offer it in the State of New York," said Panna Sharma, CGI President and CEO. "This approval not only

underscores CGI's commitment to providing NGS panels that meet the highest quality of standards, but it also marks an important step for the company as we continue to serve a major market with considerable runway for growth as it is projected to reach $3.65 billion over the next six years."

As a Thermo Fisher NGS CDx Center of Excellence Program member, CGI participates in oncology-focused clinical trials. It also qualifies for early access to Thermo Fisher's pipeline of novel platforms and assays to assist with development of Oncomine-branded solutions for clinical and biopharma applications. Upon FDA approval of the tests, members are well-positioned to leverage their experience with the products and to be among the first to offer the tests to physicians.

REFERENCE

[i.] Grandview Research: https://www.grandviewresearch.com/press-release/global-lung-cancer-diagnostics-market

ABOUT CANCER GENETICS

Cancer Genetics Inc. is a leader in enabling precision medicine in oncology from bench to bedside through the use of oncology biomarkers and molecular testing. CGI is developing a global footprint with locations in the US, India and China. We have established strong clinical research collaborations with major cancer centers such as Memorial Sloan Kettering, The Cleveland Clinic, Mayo Clinic, Keck School of Medicine at USC and the National Cancer Institute.

The Company offers a comprehensive range of laboratory services that provide critical genomic and biomarker information. Its state-of-the-art reference labs are CLIA-certified and CAP-accredited in the US and have licensure from several states including New York State.

For more information, please visit or follow CGI at:
Internet: www.cancergenetics.com
Twitter: @Cancer_Genetics
Facebook: www.facebook.com/CancerGenetics

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements related to Cancer Genetics' strategic focus and the future development, commercialization and outcomes associated with its tests and testing services.

Any statements that are not historical fact (including, but not limited to, statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, risks of cancellation of customer contracts or discontinuance of trials, risks that anticipated benefits from acquisitions will not be realized, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, maintenance of intellectual property rights and other risks discussed in the Cancer Genetics, Inc. Form 10-K for the year ended December 31, 2016 and the Form 10-Q for the Quarter ended September 30, 2017 along with other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof.

Cancer Genetics, Inc. disclaims any obligation to update these forward-looking statements.

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