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Cancer Genetics, Inc. Launches FDA-Approved Universal Companion Diagnostic for Lung Cancer Leveraging Thermo Fisher's Next Generation Sequencing Panel Oncomine Dx Target Test

- CGI is one of the first laboratories in the nation to offer the 23 gene test
- CGI is working with both pharmaceutical partners and clinical cancer centers to drive usage and adoption
- Eliminates need for multiple tests to assess and monitor patients in clinical care

LOS ANGELES, June 27, 2017 (GLOBE NEWSWIRE) -- Cancer Genetics, Inc. (Nasdaq:CGIX) (“CGI” or “The Company”), a leader in enabling precision medicine for oncology through molecular markers and diagnostics, announced today the launch of Thermo Fisher Scientific's (Thermo Fisher) Oncomine Dx Target - the first next-generation sequencing (NGS)-based Companion Diagnostic (CDx) test that simultaneously screens tumor samples for biomarkers associated with three FDA-approved therapies for non-small cell lung cancer (NSCLC). CGI is one of the first laboratories, one of only three, in the USA to offer Thermo Fisher’s Oncomine Dx Target Test.

Lung cancer is by far the leading cause of cancer death among both men and women; about 1 out of 4 cancer deaths are from lung cancer. It is the second most common cancer in both men and women (not counting skin cancer). About 14% of all new cancers are lung cancers, with NSCLC accounting for 85% of all lung cancers.[1] It is estimated that in 2017, approximately 222,500 Americans will be diagnosed with lung cancer, and almost 156,000 will die from this disease.[2]

Approved by the FDA on June 22 of 2017, theOncomine Dx Target Test simultaneously evaluates 23 genes clinically associated with NSCLC. Following FDA approval, results from analysis of three of these genes can now be used to identify patients who may be eligible for treatment with one of the following: AstraZeneca's EGFR inhibitor Iressa (gefitinib), Pfizer's ALK and ROS1 inhibitor Xalkori (crizotinib), and the combination therapy of Novartis' MEK inhibitor Mekinist (trametinib) and RAF inhibitor Tafinlar (dabrafenib). With this test, physicians can now match patients to these therapies in days instead of several weeks, which it often takes when screening samples one biomarker at a time.

Recognized as Thermo Fisher's NGS CDx Center of Excellence, CGI is among the first 3 laboratories that will offer the Oncomine Dx Target Test as a service to oncologists. All tests will be run on Thermo Fisher's Ion PGM Dx System, which received FDA 510(k) clearance in parallel for use on formalin-fixed, paraffin-embedded (FFPE) tissue samples. The Oncomine Dx Target Test is a kit and requires as little as 10 nanograms of DNA from FFPE tissues

samples - a critical advantage of the test, given the challenge of NSCLC patient samples often being of limited quantity.

The test report will not only indicate whether patients have ROS1, EGFR, and BRAF alterations linked to the three FDA-approved treatments, but also the presence or absence of gene variants in 20 other genes associated with NSCLC that are currently investigated in clinical trials and potentially actionable in the future.

Dr. Shereen Gheith, Chief of Section of Molecular Pathology and Section of Hematopathology at Health Network Laboratories stated, "The Oncomine Dx Target Test is an important new capability for the global medical community and another significant step in the growth of CGI as an extremely qualified resource for the management of cancer patients nationwide. CGI's 21st century molecular technologies, speed, and world-class medical environment bring increased hope to cancer patients for improved outcomes."

"We are very pleased to be able to add the Oncomine Dx Target Test to our comprehensive menu of cutting edge diagnostic services available to physicians, and to be one of the first 3 labs to provide rapid access to this test. NGS has revolutionized cancer research by providing a comprehensive method of detecting genomic alterations associated with somatic cancer. By becoming a companion test, the Oncomine Dx Target Test represents an important advance in precision medicine as a rapid and comprehensive tool guiding clinicians in treatment decision-making. CGI has an extensive heritage in biomarker and molecular profiling for lung cancer. The addition of this comprehensive new CDx to our test menu will aid in further streamlining of our operations to get results in a rapid timeframe so that the patients don’t have to wait, in contrast to the sequential testing approach," said CGI President and CEO Panna Sharma.

According to Thermo Fisher, this initial approval will enable the company to work quickly to expand the test's indications into new drug/biomarker combinations, including applications beyond lung cancer.

[1] Julian R. Molina, et al. Non–Small Cell Lung Cancer: Epidemiology, Risk Factors, Treatment, and Survivorship. *Mayo Clin Proc.* 2008 May; 83(5): 584–594.

[2] American Cancer Society, Cancer Facts and Figures 2017; page18. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf

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
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Forward-Looking Statements:
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements pertaining to Cancer Genetics Inc.'s expectations regarding the completion, timing, pricing and size of the offering described in this press release constitute forward-looking statements.

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, 2015 and the Form 10-Q for the Quarter ended March 31, 2016 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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