Cancer Genetics, Inc. Receives New York State Licensure for FHACT(R) Cervical Cancer Test

RUTHERFORD, N.J., April 16, 2015 (GLOBE NEWSWIRE) -- Cancer Genetics, Inc. (Nasdaq: CGIX) ("CGI" or "The Company"), an emerging leader in DNA-based cancer diagnostics, announced today that its proprietary FISH-based HPV-Associated test for cervical cancer (FHACT®) has received conditional licensure from the New York State Department of Health. This marks a significant commercial milestone for Cancer Genetics, as it allows the company to market the test to gynecologists, oncologists, and women’s health centers serving more than 7.6 million women in New York State.

Each year in the US, more than 55 million Pap smears are performed, about 3.5 million of which have abnormal or unclear results. While cervical cancer screening protocols are relatively well established, there remains a significant unmet need to supplement current screening methods with tests that can better predict progression to advanced cervical disease. CGI’s FHACT® test, which assesses genomic changes commonly found in cervical cancers, can help identify those women who are at higher risk for disease progression. FHACT® can also help drive a reduction in unnecessary colposcopies and cervical biopsies, minimizing the over-treatment of women who do not show the genomic abnormalities associated with pre-cancerous and cancerous lesions. A unique feature of the test is that it can be performed on the same specimen collected during routine women’s health exams (Pap smear), making it significantly less invasive than traditional colposcopy-guided biopsies.

"There continues to be a significant unmet need for more definitive and genomically informed diagnosis of cervical cancer," said Panna Sharma, CEO of Cancer Genetics, Inc. "Our proprietary cervical cancer test, FHACT®, is designed to respond to this need. Receiving New York State licensure for FHACT® will allow us to expand our efforts to drive greater adoption of the test in the United States."

Cancer Genetics is actively pursuing a number of initiatives to increase the utilization of the FHACT® test for cervical cancer screening. The Company is engaged in four major collaborations with leading medical centers to validate the clinical outcomes resulting from the use of the FHACT®. Data from ongoing clinical studies with the National Cancer Institute (NCI) and Kamenini Hospital in India is anticipated later this year. Additionally, CGI is expanding its sales and marketing efforts to clinicians and pathology laboratories in North America and India to provide increased access to the FHACT® test. In 2014, the company received two patents covering the FHACT® test design and its clinical application on patient samples, underscoring the novelty of the test. FHACT® also
received CE marking in 2014, permitting the test to be sold in the European Union (EU).

More information about FHACT® is available at www.cgifhact.com.

About Cancer Genetics

Cancer Genetics, Inc. is an emerging leader in DNA-based cancer diagnostics, servicing some of the most prestigious medical institutions in the world. Our tests target cancers that are difficult to diagnose and predict treatment outcomes. These cancers include hematological, urogenital and HPV-associated cancers. We also offer a comprehensive range of non-proprietary oncology-focused tests and laboratory services that provide critical genomic information to healthcare professionals, as well as biopharma and biotech companies. Our state-of-the-art reference labs are focused entirely on maintaining clinical excellence and are both CLIA certified and CAP accredited and have licensure from several states including New York State. We have established strong research collaborations with major cancer centers such as Memorial Sloan-Kettering, The Cleveland Clinic, Mayo Clinic and the National Cancer Institute.

For more information, please visit or follow us:

Internet: http://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. All statements pertaining to future financial and/or operating results, future developments in research, technology, clinical development and potential opportunities for Cancer Genetics, Inc. tests and services, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management 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, 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 Company’s Form 10-K for the year ended December 31, 2014 along with other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. Cancer Genetics disclaims any obligation to update these forward-looking statements.

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