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# Cancer Genetics Launches Comprehensive Immuno-Oncology Testing Portfolio For Use in Clinical Trials, Translational Research, and Therapy Selection for Patients

- Immuno-oncology drugs are expected to reach \$35 billion in sales by 2024 and potentially impact up to 60% of all cancer patients
- Cancer Genetics, Inc. will offer immuno-oncology marker testing and technologies for both solid tumors and blood based cancers

RUTHERFORD, N.J. and LOS ANGELES, Jan. 21, 2016 (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 that it has developed and launched a comprehensive portfolio of tests and technologies to help measure and monitor immuno-oncology markers and select patients for targeted therapies. This portfolio will be available for clinical trials, patient care, and translational research utilizing multiple technological platforms and will be available at CGI's New Jersey and Los Angeles facilities. In addition, the newly acquired *Center of Excellence For Solid Tumor Testing* based in Los Angeles, formerly Response Genetics, will also offer the FDA-approved PDL-1 antibody for selection of patients that are most likely to benefit from key immuno-oncology drugs.

Immuno-oncology is a highly promising area of medicine and has already seen several blockbuster therapies enter the market in disease areas such as non-small cell lung cancer and melanoma. Several of these drugs require identification of patients that have a high likelihood of response. As a result, healthcare professionals require identification and potentially companion diagnostics to facilitate patient care. Clinical trials, targeted therapies that are under development, and many existing approved oncology drugs are undergoing clinical research to identify patient groups that can benefit from stimulating an effective immune response against cancer. The goal is to achieve a more durable or more effective response to the therapy.

Immuno-oncology drugs by themselves have been shown to be highly effective in 20 to 30 percent of patients, and combination therapies are bringing the promise of more significant patient benefits. In order to develop more effective treatments with fewer side effects, immune-oncology biomarkers and tests helping to assess the effects of therapies will play a key role.

Wall Street analysts are projecting over \$35 billion in annual worldwide sales for immuno-oncology drugs by 2024, which would account for half of all spending on cancer drugs, according to market research firm IMS Health. According to pharmaceutical analysts, major

pharmaceutical multinational companies are all expected to spend nearly \$1 billion a year on immuno-oncology research, early access, and development programs and clinical trials. CGI offers the entire portfolio of immuno-oncology testing and technologies to help pharmaceutical and biotech companies accelerate their clinical trials by integrating immune response data with the genomic and biomarker data that CGI currently provides. This integrated offering will be critical in expanding the CGI value proposition to biotech and pharma companies and increasing the total addressable market for CGI.

“In an era of precision and increasingly personalized therapy, the healthcare industry demands cost-effective options that can robustly identify biomarkers to help select cancer patients most likely to benefit from the emerging class of immuno-oncology drugs,” said Panna Sharma, President and CEO. “CGI has prepared an extensive portfolio of technologies ranging from Immunohistochemistry (IHC) and immuno-phenotyping by flow cytometry to RNA-sequencing. These technologies address the tremendous demand we are experiencing by providing both genomic and immune-marker information to clinical trials and patient care.”

The CGI portfolio of immuno-oncology tests includes immunohistochemistry (IHC)-based tests that can detect novel biomarkers like PD-1 and PD-L1 and flow cytometry-based tests and panels that can assess immune response against cancers by evaluating subsets of immunomodulatory and effector cells. CGI also offers a next generation sequencing (NGS)-based targeted RNA sequencing test that can measure expression levels of drug targets, tumor infiltrate composition, and total immune cell composition. Many of these assays are also available for clinical use and are CLIA- and New York State-approved.

Several drugs targeting PD-1/PD-L1 interactions are currently either FDA approved or in clinical trials. Assessment of PD-L1 expression on tumor cells and in tumor microenvironments is currently used as a biomarker for immunotherapies in patients who fail first-line treatment for non-small cell lung cancer (NSCLC), melanoma, colon cancer, bladder cancer, and hematologic malignancies, among others.

CGI now offers commercial assays for anti-PD-L1 staining and assessment using IHC on formalin-fixed paraffin-embedded (FFPE) tissue for multiple tumor indications, including non-small cell lung cancer (NSCLC), colon adenocarcinoma, melanoma, and several subtypes of non-Hodgkin lymphoma. The in-house expertise of surgical and hemato-pathologists allows reliable evaluation of these markers using complex scoring schemes. Additionally, CGI has capabilities and reporting to integrate genomic and other biomarker data with the immune-marker status to provide a systems approach to measuring and monitoring patients.

CGI will continue expanding the overall capabilities in immuno-oncology and immunotherapy and integrate these capabilities with the genomic and biomarker-based testing being provided in both its New Jersey and Los Angeles centers of excellence.

### **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: <http://www.cancergenetics.com> □

Twitter: @Cancer\_Genetics □

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### **Forward Looking Statements**

This presentation 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 growth in research, technology, clinical development and potential opportunities for Cancer Genetics, Inc. products 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, 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. Forms 10-K for the year ended December 31, 2014 and 10-Q for the quarter ended September 30, 2015 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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