Cancer Genetics’ Unique Tissue of Origin Test (TOO®) Receives Special FDA 510(k) Clearance

RUTHERFORD, N.J., April 16, 2018 (GLOBE NEWSWIRE) -- Cancer Genetics, Inc. (Nasdaq:CGIX), a leader in enabling precision medicine for oncology through molecular markers and diagnostics, today announced that it has received special 510(k) clearance from the U. S. Food and Drug Administration (FDA) for its Tissue of Origin test (TOO®) following modifications made to test reagents and software.

TOO® is a microarray-based gene expression test that analyzes a tumor's genomic information to help identify its origin, which is valuable in classifying metastatic, poorly differentiated, or undifferentiated cancers. TOO® assesses 2,000 individual genes, covering 15 of the most common tumor types (representing 58 morphologies) and 90% of all solid tumors [1]. These tumors include thyroid, breast, non-small cell lung, pancreas, gastric, colorectal, liver, bladder, kidney, non-Hodgkin's lymphoma, melanoma, ovarian, sarcoma, testicular germ cell, and prostate.

TOO® is the only FDA-cleared test of its type and is Medicare-reimbursed. It is also the only test that provides a pathologist's review and interpretation of a patient's test results and diagnosis. TOO® provides extensive analytical and clinical validation for statistically significant improvement in accuracy over other methods, including IHC [2]. TOO® results lead to a change in patient treatment 65% of the time. In challenging cancers that require a second round of IHC, TOO® increases diagnostic accuracy and confidence in site-specific treatment decisions [1].

"Our TOO® Test represents a unique offering with the ability to add significant value to the continuum of care for cancer patients and greatly enhance our biopharma partners' development efforts. This 510(k) clearance represents an important milestone toward our goal of gaining broad adoption of the test," said John A. (Jay) Roberts, Interim Chief Executive Officer and COO of Cancer Genetics. "An important element of our recently implemented transformation strategy is the identification of new methods through which to monetize our world-class test portfolio. We are currently evaluating several partnering opportunities that would expand the reach of the TOO® Test and have the potential to generate high-margin revenue streams. We look forward to continuing this process as we leverage the capabilities of TOO® to drive future growth."

Compared to the early version, the current TOO® assay uses new labeling reagents and has a higher accuracy rate and a shorter workflow with similar precision and reproducibility. The low RNA input requirement of the early version is maintained. The
combined result of these new features offers a further optimized clinical assay to help clinicians make diagnostic decisions and subsequent treatment selections.

Rita Shaknovich, Chief Medical Officer of CGI added, "Despite increasing excellence in the diagnostic workup for malignancies, there are approximately 150,000 newly diagnosed cases of metastatic cancer with unclear diagnosis in the U.S. and Europe each year [3]. Increasingly complex algorithms and testing associated with a diagnostic workup also means that many challenging cases have insufficient amount of sample material for analysis. CGI's TOO® aids in identifying the source of such challenging tumors while using less material, and could be used as a confirmatory tool both for routine clinical testing and for clinical trial enrollment of patients with such tumors, enabling them to be considered for novel drug therapies."

The Company announced on April 2, 2018 that it has engaged Raymond James & Associates, Inc. as a financial advisor to assist with evaluating options for the Company's strategic direction. These options may include raising additional capital, the acquisition of another company and / or complementary assets, the sale of the Company, or another type of strategic partnership. The Company's Board of Directors is committed to evaluating all potential strategic opportunities and to pursuing the path most likely to create both near- and longer-term value for Cancer Genetics' shareholders.


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. 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, 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.

Source: Cancer Genetics, Inc.