

# **Cancer Genetics, Inc. Launches Focus::Renal™, a Unique, Comprehensive and Highly Sensitive Next Generation Sequencing (NGS) Panel for Enabling Precision and Personalized Medicine in Renal Cancers**

- **Cancer Genetics, Inc. received CLIA approval for Focus::Renal™, a unique, highly sensitive and comprehensive NGS panel for renal cancer.**
- **Focus::Renal™ was developed as a result of multiple independent validations and collaborations with leading cancer centers and academic institutions, including Memorial Sloan Kettering Cancer Center (MSKCC), Cleveland Clinic, Huntsman Cancer Center at University of Utah, and University Hospital of Paris.**
- **Focus::Renal™ is the only NGS panel to simultaneously detect genome-wide copy number changes, SNP genotypes along with mutations in 76 renal cancer-related genes, covering relevant drug pathways.**

RUTHERFORD, N.J., Nov. 02, 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 the successful CLIA validation and approval of its next generation sequencing (NGS) assay that enables an era of precision medicine for renal cancers, Focus::Renal™. Focus::Renal™, a highly-sensitive NGS panel, detects mutations of 76 renal cancer-related genes, as well as genome-wide copy number changes, and critical single nucleotide polymorphisms (SNPs), all in a single test, that enable precision diagnosis, prognosis, and therapy selection for renal cancer patients.

Renal cancer accounts for 5% of adult cancers in the United States with an estimated 62,700 new cases and 14,240 deaths in 2016 [1]. The most common renal neoplasm is renal cell carcinoma (RCC). Clear cell RCC (ccRCC) accounts for ~75% of RCC, with malignant subtypes papillary RCC (pRCC) and chromophobe RCC (chrRCC), and the benign neoplasm oncocytoma (OC) mostly comprising the remainder. ccRCC has a poorer prognosis than papillary and chromophobe RCC malignant subtypes. About one fourth of the patients with ccRCC present with metastatic disease at diagnosis while 20-40% of those with locally confined tumor tend to develop metastasis.

There are seven FDA-approved targeted therapies (including VEGF-TKIs, anti-VEGF monoclonal antibody, and mTOR inhibitors) and one immunotherapy (anti-PD1 checkpoint inhibitor) available to date to treat metastatic RCC – which makes therapy selection more challenging and yet more critical. Currently, there is a growing body of evidence showing that mutations, copy number changes, and certain polymorphisms correlate with patient outcome

and therapy response, and can be critical in enabling precision medicine. In addition, there are over 200 open clinical trials enrolling patients with renal cancers. At present, comprehensive genomic profiling of renal cancer patients has become an important need due to its potential impact on precision diagnostics and the development of tailor-made therapies, resulting in improved cancer care.

Focus::Renal™ is a unique NGS panel, developed by CGI in collaboration with leading cancer centers and academic institutions, including MSKCC, Cleveland Clinic, Huntsman Cancer Center at University of Utah, and University Hospital of Paris. Focus::Renal™ is a comprehensive and accurate genomic profiling tool covering the majority of renal cancer markers and pathways. Focus::Renal™ is designed based on the most current scientific literature, TCGA genomic data, and in-house findings as a result of collaborations with leading research institutions, and has undergone multiple independent validations using samples from over 500 patients. The test can be performed on a wide variety of patient specimen types, such as needle biopsies, fine-needle aspirates, and resected specimens using both formalin-fixed paraffin-embedded (FFPE) and fresh/fresh-frozen specimens, including the ones with minimal starting material, giving clinicians a choice on how to incorporate the test into their diagnostic workflow. The Focus::Renal™ NGS panel can be utilized to distinguish among the dominant 3 malignant and 1 benign renal cancer subtypes, which is today largely driven by morphological and immunohistochemical review.

"Focus::Renal™ has the ability to significantly facilitate the personalized care for renal cancer patients and also generate future insights; as the deeper understanding of molecular abnormalities will enhance the development of more effective therapies for RCC. Implementing precision medicine for kidney cancer patients requires powerful and targeted tools like Focus::Renal™. Our immediate plans include collaborations with biopharma and academic partners to implement Focus::Renal™ for liquid biopsies so that this critical test can also inform cancer care directly from blood," said Panna Sharma, Chief Executive Officer and President of CGI.

[1] Siegel RL, Miller KD, Jemal A: Cancer statistics, 2016. CA Cancer J Clin. 2016 Jan-Feb;66(1):7-30.

## **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](http://www.cancergenetics.com)

Twitter: [@Cancer\\_Genetics](https://twitter.com/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 future financial and/or operating results and potential for our tests and services, and future revenues or growth 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 June 30, 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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