Invitae partners with KEW, Inc. to develop somatic mutation detection capabilities to improve cancer care by providing comprehensive genomic information

-- Combining germline and somatic information provides more comprehensive view from diagnosis through treatment --

-- Detailed genomic characterization of tumors rapidly enhancing drug development through biomarker-driven clinical trials --

Invitae Corporation (NYSE: NVTA) and KEW, Inc. today announced a collaboration to develop comprehensive genomic profiling solutions for sequencing tumor DNA on Invitae’s next generation sequencing (NGS) platform. By adding KEW’s somatic mutation detection capabilities to Invitae’s extensive portfolio of diagnostic genetic testing panels for hereditary cancers, Invitae will be able to help clinicians guide their patients from initial cancer diagnosis through treatment and monitoring.

The genetics of both a patient and tumor play an important role in making cancer treatment decisions and informing drug development. Germline testing from Invitae assesses inherited genetic changes that increase the risk of developing certain cancers. Somatic testing from KEW analyzes acquired alterations in DNA within a tumor that can drive its growth. Together, the tests have the potential to provide detailed genetic information on each patient’s unique situation.

KEW’s CANCERPLEX® sequencing assay for genomic profiling of tumors helps a clinician better understand the specifics of a patient’s cancer by:

- Optimizing detection of somatic mutations in 435 cancer-associated genes
- Identifying clinically-actionable mutations not found by hot-spot testing
- Determining accurate tumor mutation burden and microsatellite instability for identifying likely responders to immune checkpoint inhibitors.

Invitae will fund the collaborative development efforts and the build-out of its production capabilities to integrate KEW’s technology into its platform and workflow. In addition to KEW’s CANCERPLEX® sequencing assay, Invitae gains access to KEW’s proprietary bioinformatics software providing robust, high-performance analytics for sequence alignment and variant calling as well as state-of-the-art software for curating genomic mutations and biomarkers.

“With an industry-leading diagnostic cancer offering now nearly twice as large as that of our nearest competitors available at a fraction of the cost, we are seeing increased demand from existing clients and potential partners to apply the same formula to somatic testing to expand
access and increase utility in cancer care and research,” commented Sean George, Invitae’s chief executive officer. “Broadening our ability to capture genetic information on both tumor biology and a patient’s inherited risk of disease while maintaining our commitment to lowering cost enhances Invitae’s ability to expand the market and enable affordable, high-quality precision care for more patients.”

“Comprehensive genomic profiling is emerging as the gold standard for matching the right patient with the right drug at the right time, but cost and accessibility continue to limit its potential and prevent most patients from benefiting from these technological advancements,” said Jerry Williamson, president and chief executive officer of KEW, Inc. “We share Invitae’s commitment to making somatic testing an integral part of cancer care and believe that requires not only delivery of high-quality data sets but also world-class medical interpretation at scale. State-of-the-art bioinformatics has enabled Invitae to build out a uniquely scalable offering well suited to rapid integration with our proprietary algorithms for optimal and accurate genomic variant detection and curated knowledge base. We believe aligning these capabilities on a single platform will provide the basis for making molecular characterization the standard of care.”

Invitae offers the broadest hereditary oncology testing menu available. Testing of these genes may help improve care by informing screening and prevention strategies, early diagnosis, and guiding treatment choices to increase the chances of successful treatment and survival. Among Invitae’s hereditary cancer panels are:

- Guidelines-based panels for breast, prostate, gynecologic, and colorectal cancers;
- Breast cancer STAT panels to inform surgical and medical management decisions, which provide results in 5–12 calendar days (7 days on average) from sample receipt. These panels include the option to re-requisition additional genes if needed within 90 days of receiving the STAT report; and
- Other tests for hereditary risk of brain, breast and gynecologic, endocrine, gastrointestinal, genitourinary, hematologic, pediatric, and skin cancers.

Cancer includes many different risk factors, with genetics playing a role in both development and progression of the disease. Approximately 5% to 10% of all cancers are hereditary. An additional 10% to 30% of cancer patients have a close family member who also had cancer, suggesting a familial link even though no specific hereditary link is found. A large portion of cancer patients have what’s called sporadic cancer, meaning the cancer does not seem connected to inherited genetic traits, or may be the result of many different factors. In addition to playing a role in diagnosing and treating an individual with cancer, genetic information can be used to help inform health decisions for that person’s family members.

About KEW, Inc.

KEW, Inc. is a privately-held comprehensive genomic profiling company with headquarters in Cambridge, MA, dedicated to revolutionizing cancer care by providing therapeutic options based
on an individual patient's tumor genomic profile. CANCERPLEX® is KEW’s flagship clinical product family for sequencing and identifying applicable targeted therapies and clinical trials. The Company’s Powered-by-KEW℠ solutions offer expanded access to CANCERPLEX in partnership with local molecular pathology laboratories including qualified reagents, proprietary bioinformatics, a custom curated knowledge database, and comprehensive clinical reporting.

About Invitae

Invitae Corporation (NYSE: NVTA) is bringing comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. As one of the fastest growing genetic information company, Invitae is advancing the broad potential of genetics, helping to expand its use across the healthcare continuum. The company provides genetic information services for all stages of life – from preconception screening, to newborn diagnosis, to inherited disease screening, to proactive health management – and a unique, rapidly expanding network of patients, hospital systems, and advocacy partners that is moving genetics from one-dimensional testing to complex information management. For more information visit www.invitae.com, or follow us on Twitter, Facebook or LinkedIn.

Invitae Corporation Safe Harbor Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of adding KEW’s somatic detection capabilities to the company’s portfolio of diagnostic genetic testing panels, including providing a basis for making molecular characterization the standard of care; and that KEW’s offering is well-suited to rapid integration with Invitae’s custom screening and interpretation solutions. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the company’s ability to develop and commercialize new tests and expand into new markets; the company’s ability to successfully offer KEW’s testing and demand for such tests; the company’s ability to continue to lower costs and expand the market for affordable, high-quality testing for more patients; the risk that the company may not obtain or maintain sufficient levels of reimbursement for its tests; the company’s ability to compete; the company’s inability to raise additional capital on acceptable terms; the company’s history of losses; risks associated with the company’s ability to use rapidly changing genetic data to interpret test results accurately, consistently, and quickly; risks associated with the company’s limited experience with respect to acquisitions; demand for the company’s tests; the company’s failure to manage growth effectively; the company’s need to scale its infrastructure in advance of demand for its tests and to increase demand for its tests; security breaches, loss of data and other disruptions; laws and regulations applicable to the company’s business; and the other risks set forth in the company’s filings with the Securities and Exchange Commission, including the risks set forth in the company’s Annual Report on Form 10-K for the year ended December 31, 2017. These forward-looking statements speak only as of the date hereof, and Invitae Corporation disclaims any obligation to update these forward-looking statements.