



Fulgent Genetics Announces Launch of Next Generation Sequencing (NGS) Test to Detect Coronavirus Disease (COVID-19)

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Fulgent Genetics will partner with MedScan Laboratory to launch one of the market's first COVID-19 tests based on comprehensive Next Generation Sequencing technology

TEMPLE CITY, Calif., March 17, 2020 (GLOBE NEWSWIRE) -- Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent Genetics" or the "company"), a provider of comprehensive genetic testing and Next Generation Sequencing ("NGS") solutions, today announced the launch of a Next Generation Sequencing based test for the Coronavirus Disease (COVID-19). Fulgent's NGS test will be one of the market's first diagnostic tests for the COVID-19 virus developed based on NGS technology. Fulgent and MedScan will begin accepting specimens for testing this week from healthcare providers, clinics and reference labs.

Built on advanced Next Generation Sequencing (NGS) technology, Fulgent's COVID-19 test will be more comprehensive compared to Reverse Transcriptase-Polymerase Chain Reaction ("RT-PCR") tests on the market. Fulgent's test will sequence the entire viral genome, creating hundreds of targets versus just a few for RT-PCR tests. In addition, Fulgent's test will not be limited by a shortage of reagents, which has proven to be a roadblock for large scale processing of RT-PCR based tests in the market currently. Fulgent estimates that its lab will have capacity to process thousands of samples per day.

MedScan Laboratories is a CLIA certified lab that will collect samples on behalf of Fulgent and extract RNA for processing. Fulgent will sequence the viral genome, analyze samples and provide comprehensive reports back to healthcare providers.

"The surge in cases of COVID-19 in the U.S. and around the world has created an urgent need for accurate diagnostic testing solutions for the viral disease," said Dr. Harry Gao, Chief Scientific Officer at Fulgent Genetics. "We believe our NGS-based test for COVID-19 will arm healthcare providers with a better solution for accurately diagnosing cases of the disease. In addition, the virus mutation data we collect from this NGS based test could be extremely valuable to researchers in the future to predict the clinical outcome and potentially develop treatment options and vaccines for this virus."

Fulgent Genetics is uniquely well-positioned to develop and offer a Next Generation Sequencing based test for COVID-19 given the company's presence on the ground in China through its joint venture, which has provided access to real positive controls and unique data insights from patients in China.

Fulgent Genetics' joint venture in China, which was established in 2016, recently executed a research agreement for COVID-19 with the Chinese Academy of Medical Sciences and Peking Union Medical College Hospital ("PUMCH"), both for diagnostic and mutation analysis of the virus. Fulgent Genetics, through its China JV and with strong cooperation with PUMCH, began collecting patient samples beginning January of 2020 from the most affected regions of China for research, development, analysis, testing, and validation. Leveraging Fulgent's NGS-based test, a large-scale study on these samples is ongoing to better understand how the virus sequence changes over time, and the association of virus mutations with clinical outcomes. The data may also help to predict pathogenicity and infectivity to assist in future drug or vaccine development.

Fulgent plans to submit its NGS test to the U.S. Food and Drug Administration (FDA) for validation and emergency use authorization in the coming weeks. While FDA approval is not required for labs to collect samples and perform diagnostic testing, such approval could help to facilitate broader adoption of the test.

For more information about COVID-19 testing options from Fulgent Genetics and MedScan Laboratories, please visit www.fulgentgenetics.com/COVID19 or email the Fulgent team directly at covid19@fulgentgenetics.com.

Providers should refer to the most current CDC guidelines for further information on appropriate testing of patients, available here www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html.

About Fulgent Genetics

Fulgent Genetics is a growing technology company with an initial focus on offering comprehensive genetic testing to provide physicians with clinically actionable diagnostic information they can use to improve the quality of patient care. The company has developed a proprietary technology platform that integrates sophisticated data comparison and suppression algorithms, adaptive learning software, advanced genetic diagnostics tools and integrated laboratory processes. This platform allows the company to offer a broad and flexible test menu and continually expand and improve its proprietary genetic reference library, while maintaining accessible pricing, high accuracy and competitive turnaround times. The company believes its current test menu, which includes

approximately 18,000 single-gene tests and more than 850 pre-established, multi-gene, disease-specific panels, offers more genes for testing than its competitors in today's market, which enables it to provide expansive options for test customization and clinically actionable results.

About MedScan

MedScan laboratory is located in Williston, ND. It was started in 1999 as a toxicology lab testing for drugs of abuse. Since that time MedScan has grown to service accounts in every state with the exception of New York. MedScan utilizes the most advanced technology in the toxicology market which allows it to have some of the lowest detection limits in comparison to their competitors. MedScan also performs an extensive array of blood tests for their clients. In 2016, Medscan started its sister company, Altru Diagnostics, in Houston, TX to expand their testing capabilities to include molecular and genetic testing.

About Peking Union Medical College Hospital

Peking Union Medical College Hospital (PUMCH) is a Class A tertiary comprehensive hospital committed to delivering state-of-the-art clinical care, innovative scientific research and rigorous medical education. It is designated by the Chinese National Health Commission as one of the national referral centers offering diagnostic and therapeutic care of complex and rare disorders, national demonstrative bases for higher medical education and standardized residency training, core national for clinical research and technological innovation, as well as one of the earliest Chinese hospitals offering medical care to senior leaders and foreign patients. PUMCH enjoys high reputation for its full range of disciplines, cutting-edge technologies and outstanding specialties. According to "China's Hospital Rankings" released by Hospital Management Institute, Fudan University, PUMCH has topped the ranking for consecutively 10 years.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements in this press release include statements about, among other things: anticipated timing, availability, demand for and effectiveness of the company's testing products for COVID-19.

Forward-looking statements are statements other than historical facts and relate to future events or circumstances or the company's future performance, and they are based on management's current assumptions, expectations and beliefs concerning future developments and their potential effect on the company's business. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: the market potential for, and the rate and degree of market adoption of, the company's tests and genetic testing generally; the company's ability to maintain the low internal costs of its business model; the company's ability to maintain an acceptable margin on sales of its tests, particularly in light of increasing competitive pressures and other factors that may continue to reduce the company's sale prices for and margins on its tests; risks related to volatility in the company's results, which can fluctuate significantly from period to period; the company's investments in its infrastructure, including its sales organization and operational capabilities, and the extent to which these investments impact the company's business and performance and enable it to manage any growth it may experience in future periods; the company's level of success in obtaining coverage and adequate reimbursement and collectability levels from third-party payors for its tests; the company's level of success in establishing and obtaining the intended benefits from partnerships, joint ventures or other relationships; the company's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; risks associated with the company's international operations; the company's ability to protect its proprietary technology platform; and general industry, economic, political and market conditions. As a result of these risks and uncertainties, forward-looking statements should not be relied on or viewed as predictions of future events.

The forward-looking statements made in this press release speak only as of the date of this press release, and the company assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law.

The company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2019 and the other reports it files from time to time, including subsequently filed quarterly and current reports, are made available on the company's website upon their filing with the Securities and Exchange Commission. These reports contain more information about the company, its business and the risks affecting its business.

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For More Information on Fulgent's COVID-19 NGS Test:

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Source: Fulgent Genetics, Inc.