Fulgent Genetics Launches New Beacon787 Expanded Carrier Screening Panel

February 28, 2023

New 787 gene panel becomes the largest panel available on Fulgent Genetics' platform, setting a new standard for patients seeking the most comprehensive option for carrier screening

TEMPLE CITY, Calif.--(BUSINESS WIRE)--Feb. 28, 2023-- Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent" or the "Company"), a technology-based company with a well-established clinical diagnostic business and a therapeutic development business, today announced the immediate availability of their new Beacon787 expanded carrier screening panel. Beacon787 will include a total of 787 genes associated with autosomal recessive and X-linked conditions. Included in this panel are all of the American College of Medical Genetics and Genomics (ACMG) tier 3 genes, which ACMG published in their latest practice guideline for carrier screening, recommending that all pregnant patients and those planning a pregnancy be offered this set of genes as an equitable, pan-ethnic screening approach. The ACMG list includes genes with carrier frequency of >1/200 for autosomal recessive conditions and disease prevalence of >1/40,000 for X-linked conditions. Leveraging Fulgent's proprietary platform and informatics, Beacon frequently excels as it relates to analytical detection rates, ability to discern pseudogenes, and reliable copy number calls.

"This is an important product launch for our company and a big step forward in carrier screening," said Brandon Perthuis, Fulgent's Chief Commercial Officer. "With our technology platform, we can offer this complex panel while still delivering a rapid turnaround time. For clinicians and patients looking for the most comprehensive carrier test, Beacon787 is a great option. With many couples now testing in tandem, we can quickly return results on both partners, identifying scenarios of high-risk versus low-risk. We are proud to lead the way in carrier screening development and look forward to helping our patients and their providers with their reproductive testing needs."

Fulgent's optimized workflow for variants with pseudogene interference has been validated and externally published as a method for analysis of genes with pseudogene interference and/or sequence homology issues, allowing for improved testing accuracy. This method also optimizes the turnaround time and reduces the need for unnecessary confirmatory testing to identify point mutations, copy number variants, and gene conversion events in genes with pseudogene interference that other labs may not be able to detect. Using this pipeline, Fulgent can quickly distinguish positive and negative cases with NGS sequence misalignment and avoid testing delays due to redundant confirmatory testing. In contrast, most bioinformatics methods do not discriminate genomic regions with extensive sequence homology, which can lead to false negative or false positive variant calls, and/or produce incorrect copy number calls due to misalignment of reads. Fulgent's bioinformatics algorithms compare read depth between homologous regions to identify sequence misalignment.

Carrier screening assesses the risk for individuals and couples to pass on certain genetic conditions to their children. This testing is for women or couples who are currently expecting, considering pregnancy, or planning to become pregnant in the future. Most often, carriers for these conditions do not have symptoms or a positive family history of disease. Carrier screening can identify these otherwise unknown risks and allow patients to make informed decisions about family planning. The American College of Obstetricians and Gynecologists (ACOG) recommends offering carrier screening to all women who are considering pregnancy, regardless of ethnicity or family history.

About Fulgent

Fulgent is a technology-based company with a well-established clinical diagnostic business and a therapeutic development business. Fulgent's clinical diagnostic business offers molecular diagnostic testing services, comprehensive genetic testing, and high-quality anatomic pathology laboratory services designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. Fulgent's therapeutic development business is focused on developing drug candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile of new and existing cancer drugs. The company aims to transform from a genomic diagnostic business into a fully integrated precision medicine company.

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: evaluations and judgements regarding the importance of the Beacon787 launch, the Beacon787 panel, the Company's technology platform, its other testing and testing services, the Company's business in general, its development efforts and the Company's ability to continue to provide rapid turnaround times.

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, including its Beacon787 panel; its ability to maintain turnaround times and otherwise keep pace with rapidly changing technology; the Company's ability to maintain the low internal costs of its business model; the Company's ability to maintain an acceptable margin; risks related to volatility in the Company's results, which can fluctuate significantly from period to period; risks associated with the composition of the Company's customer base, which can fluctuate from period to period and can be comprised of a small number of customers that account for a significant portion of the Company's revenue; the Company's level of success in obtaining coverage and adequate reimbursement and collectability levels from third-party payors for its tests and testing services; the Company's level of success in establishing and obtaining the intended benefits from partnerships, strategic investments, joint ventures, acquisitions, or other relationships; the success of the Company's development efforts, including the Company's ability to progress its candidates through clinical trials on the timelines expected; the Company's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; and the Company's ability to protect its proprietary technology and intellectual property. 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 U.S. Securities and Exchange Commission, or the SEC, including its annual report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022 and the other reports it files from time to time, including subsequently filed annual, quarterly, and current reports, are made available on the Company's website upon their filing with the SEC. These reports contain more information about the Company, its business, and the risks affecting its business.

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