Fulgent Genetics Receives EU CE Mark for FulgentExome & FulgentPLM

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EL MONTE, Calif.--(BUSINESS WIRE)--Jul. 17, 2025-- Fulgent Genetics, Inc. (NASDAQ: FLGT) (“Fulgent,” or the “Company”), a technology-based company with a well-established laboratory services business and a therapeutic development business, today announced it has received CE certification under the European Union (EU)’s In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR) for its germline next-generation sequencing (NGS) system, which includes FulgentExome and Fulgent Pipeline Manager (PLM). Based on available information, Fulgent may be the first laboratory to receive CE mark for one of the most comprehensive end-to-end germline testing offerings, with more than 4600 genes validated for diagnostic use.

FulgentExome is a patient-centric, phenotype-driven analysis designed to examine coding regions and splice junctions for more than 4600 genes and to report only the variants, which are of plausible clinical relevance. It is a next generation sequencing (NGS)-based system designed for clinical exome analysis to identify germline variants to aid the clinical diagnosis of suspected genetic condition(s) relevant to the patient’s clinical and family history. Fulgent PLM is an in vitro diagnostic medical device software used within the FulgentExome system to analyze genetic information derived from sequencing data.

“We are proud to announce that our germline next-generation sequencing (NGS) test has received CE certification from TÜV SÜD, which is a significant milestone in our mission to deliver comprehensive and high-quality genomic solutions for hereditary disease diagnosis in Europe,” said Harry Gao, Fulgent’s Chief Scientific Officer. “This achievement reflects our unwavering commitment to scientific excellence, patient safety, and regulatory compliance.”

“With the CE mark, we can now make FulgentExome available to clinics and hospital systems throughout Europe, helping families get answers to complex clinical phenotypes. FulgentExome may be used as an inclusion test for clinical trials and may help ensure eligibility for reimbursement pathways for public health programs under IVDR,” said Brandon Perthuis, Fulgent’s Chief Commercial Officer. “With excellent turnaround time and quality, we believe we can now present a compelling service offering in Europe. This CE mark is an important step towards growing our global business, especially in the EU.”

About Fulgent

Fulgent is a technology-based company with a well-established laboratory services business and a therapeutic development business. Fulgent’s laboratory services business includes technical laboratory and testing services and professional interpretation of laboratory results by licensed physicians. 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 diagnostic business into a fully integrated precision medicine company.

Source: Fulgent Genetics, Inc.

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