Fulgent Shares Preliminary Data from Poster Presentation at ESMO 2025 Conference

October 20, 2025

EL MONTE, Calif. --(BUSINESS WIRE)--Oct. 20, 2025-- 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 preliminary clinical data as of September 25, 2025, the preliminary data cutoff from its ongoing phase 2 clinical trial investigating FID-007 in combination with cetuximab in ≤ 2nd line treatment of patients diagnosed with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). This preliminary data will be presented on October 20, 2025, at the European Society for Medical Oncology (ESMO), held October 17th to the 21st in Berlin, Germany.

"We believe this preliminary data reinforces our mission to build a holistic platform that delivers comprehensive solutions across the cancer care continuum — from early detection, diagnostics, and monitoring to drug discovery and development," said Ming Hsieh, Chairman and CEO of Fulgent Genetics and co-founder of Fulgent Therapeutics. "We are encouraged by the steady advancement of FID-007 in oncology indications to date, while our precision diagnostics business continues to provide strong momentum as the primary driver of revenue for Fulgent."

Poster title: "A Randomized Phase 2 Study of FID-007 Plus Cetuximab in Patients with Recurrent / Metastatic Head and Neck Squamous Cell Carcinoma"

Observations in the Poster include:

As of a September 25, 2025 preliminary data cutoff date:

- 39 patients with R/M HNSCC have been randomized, of which 36 have received at least one dose of study treatment (FID-007 at 75 mg/m^2 or 125 mg/m^2 IV on Days 1, 8, 15 Q4W and cetuximab 500 mg/m^2 IV biweekly).
- FID-007 combined with cetuximab demonstrated meaningful anticancer efficacy at both dose levels for the 1L – 2L treatment of R/M HNSCC. Of the 35 patients evaluable for efficacy, the objective response rate (ORR) for the 75 mg/m^2 arm and the 125 mg/m^2 arm were 44% and 59% respectively, and 51% overall when both arms are combined. The median progression-free survival (PFS) for the 75 mg/m^2 arm and the 125 mg/m^2 arm were 9.2 months and 7.8 months, respectively. The overall PFS was 7.8 months, compared to the historical 2.3 months of the standard-of-care therapies.
- FID-007 exhibited a favorable safety and tolerability profile, with a 6% overall treatment-related serious adverse event (SAE) rate in the 36 patients evaluated for safety. Overall grade 3 and worse treatment-related adverse events were observed in ≥ 5% of patients and consisted of lymphocyte count decreased (19%), neutrophil count decreased (17%), anemia (8%), dermatitis acneiform (8%), white blood cell count decreased (8%), rash (6%), hypomagnesaemia (6%) and pneumonia (3%). Grade 1-2 peripheral neuropathy was reported in 31% of the patients. No grade 3 and above peripheral neuropathy has been reported to date.
- An optimal dose of FID-007 will be determined after data maturation to support further development of this combination therapy.

The poster will be available on the Investor Relations section of the company's website at: https://fulgentgenetics.gcs-web.com/news-events/presentations.

About FID-007

FID-007 is designed to improve the pharmacokinetics of paclitaxel (PTX), increase its water solubility, reduce formulation-related toxicity, and enhance therapeutic efficacy by encapsulating PTX with a clinically safe polyethyloxazoline (PEOX) polymer excipient. Importantly, the smaller size of FID-007 nanoparticles compared to solvent-based PTX micelles in plasma enables efficient penetration and reduced clearance within the tumor due to the enhanced permeability and retention effect, thus resulting in higher accumulation of FID-007 in the tumor tissue.

About Fulgent Pharma

Fulgent Pharma (a wholly-owned, indirect subsidiary of Fulgent Genetics, Inc.) has developed and possesses a novel nanoencapsulation technology, which includes over 40 patents and a targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile of both new and existing cancer drugs. Fulgent Pharma began as Fulgent

Therapeutics in Temple City, California, in June 2011. As the company progressed into the realm of personalized medicine, it also started delving into clinical genetic testing – a natural complement. In 2016, Fulgent Therapeutics split into two separate entities, Fulgent Pharma and Fulgent Genetics, which enabled each to better pursue their independent objectives. In 2022, Fulgent Pharma merged with Fulgent Genetics and is now focused exclusively on perfecting drug candidates for treating a broad range of cancers. Its partners in this endeavor include the University of Southern California, Moffitt Cancer Center, and the City of Hope Cancer Center, among others.

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.

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: Fulgent Pharma's research and development efforts, the expected availability of data or results of these trials and any implication that interim or preliminary data will be representative of final or future results. In particular, the data from Fulgent Pharma's Phase 2 clinical trial in this release is preliminary and subject to change and to future analysis. 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 and that initial or preliminary results from the Phase 2 trial or any clinical trial will be representative of future or final results; 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, 2024, filed with the SEC on February 28, 2025, 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, as well as its results of operations for the periods covered by the financial results included in this press release.

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