The American Medical Association Approves a New Category I CPT® Code for the HelioLiver™ Test

July 5, 2022

The approval of a CPT code establishes a reimbursement pathway for increased access to HelioLiver, a simple blood test to detect hepatocellular carcinoma (HCC) – the primary form of liver cancer

HelioLiver is currently available through a provider order – visit www.helioliver.com to learn more

IRVINE, Calif. and TEMPLE CITY, Calif., July 5, 2022 /PRNewswire/ -- Helio Genomics ("Helio"), and its commercial partner, Fulgent Genetics (NASDAQ: FLGT) ("Fulgent") announced that the American Medical Association (AMA) has issued a new Category I Current Procedural Terminology (CPT®) Proprietary Laboratory Analyses code for HelioLiver™, enabling a reimbursement pathway for potential increased access and broader adoption of innovative surveillance tests for liver cancer in the U.S. The code will become effective on October 1, 2022.

HelioLiver, launched in December 2021, is a multi-analyte blood test that incorporates cell free DNA (cfDNA) methylation patterns and serum protein markers for the detection of hepatocellular carcinoma (HCC) – the most common form of liver cancer. The provision of a CPT PLA code and expected subsequent Medicare reimbursement facilitates the seamless integration of HelioLiver into the American healthcare system, validating Helio's values-based approach to early liver cancer detection for at-risk patients and elevating the standard of care.

"Receiving a CPT PLA code for HelioLiver marks an important step towards our vision to enable widespread, affordable access of life-saving tools for at-risk populations who need clear and convenient answers about their health," said Justin Chen Li, Chief Executive Officer, Helio Genomics. "Our unique approach to AI-powered genomic insights for the early detection of cancer is now further substantiated as a critical tool for healthcare professionals with greater reimbursement potential. Access and affordability are key pillars to patient adherence to liver cancer surveillance, and Helio will continue to partner with agencies and professionals to ensure our test is meeting their standards as well as the needs of patients. We look forward to leading the charge in redefining the future of cancer through helping to identify more treatable and preventable liver cancer cases."

The CPT PLA code for HelioLiver will allow providers to efficiently conduct routine surveillance of at-risk patients and streamline the reporting of services, claims processing and development of guidelines for medical care review, ultimately advancing more sophisticated and comprehensive care for patients.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer. According to the American Cancer Society, liver cancer is the fastest growing cancer with more than 800,000 people diagnosed each year worldwide. Liver cancer is also a leading cause of cancer deaths globally, accounting for more than 700,000 deaths each year, many due to late-stage diagnosis. Detecting cancer can be a key factor to enabling potentially curative treatment options and as such, regular surveillance is recommended for the approximately 500 million people worldwide who are at-risk due to cirrhosis or hepatitis B.

Other conditions that are associated with HCC development are: hepatitis C, excessive alcohol use, nonalcoholic fatty liver disease (NAFLD), and inherited diseases such as hereditary hemochromatosis, primary biliary cholangitis (PBC), and Wilson's disease.

About HelioLiver

HelioLiver is a multi-analyte blood test that incorporates cell-free DNA (cfDNA) methylation patterns, serum protein markers, and demographic information for the detection of hepatocellular carcinoma.

Based on results from the ENCORE Phase 2 prospective, blinded, multi-center study, HelioLiver demonstrated high specificity (91%) and high sensitivity (76%) in detecting early-stage (I and II) HCC, significantly outperforming other clinically available detection tools such as AFP (57%) and GALAD (65%). Ultrasound, as standard of care, showed only 47% sensitivity for early-stage HCC.[1] When considering HCC at all stages, HelioLiver performed at an 85% sensitivity with the same 91% specificity.[1] By detecting HCC in earlier stages, HelioLiver allows patients access to more curative options and improve outcomes overall.

Fulgent Genetics (NASDAQ: FLGT) is the exclusive commercial partner to Helio Genomics for the distribution of HelioLiver, which is currently available for order as a laboratory developed test in the United States and Canada.

Providers can place orders online at helioliver.com/provider/how-to-order, via phone (+1 626-350-0537) or email at info@helioliver.com to get connected with a representative.

About Helio Genomics

Helio Genomics is an AI-driven healthcare company focused on commercializing early cancer detection tests from a simple blood draw. The company's mission is to simplify cancer screening so lives can be saved by detecting cancer earlier. With Helio's AI-driven technology, both physicians and their patients gain powerful insights from accurate, accessible, and convenient blood tests. Helio's development program is focused on liver, colon, breast and lung cancer.

Helio Genomics is headquartered in Irvine, CA, with R&D, GMP and CLIA facilities in Irvine, CA and West Lafayette, IN.

About Fulgent Genetics

Fulgent Genetics is a technology-based genetic testing company focused on transforming patient care in oncology, infectious and rare diseases, and reproductive health. Fulgent Genetics' proprietary technology platform has created a broad, flexible test menu and the ability to continually expand and improve its proprietary genetic reference library while maintaining accessible pricing, high accuracy, and competitive turnaround times. Combining next generation sequencing, or NGS, with its technology platform, the Company performs full-gene sequencing with deletion/duplication analysis in an array of panels that can be tailored to meet specific customer needs. A cornerstone of the Company's business is its ability to provide expansive options and flexibility for all clients' unique testing needs through a comprehensive technology offering including cloud computing, pipeline services, record management, web portal services, clinical workflow, sequencing as a service and automated laboratory services.

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: guidance regarding expected annual financial results, including revenues, core revenues, GAAP income, and non-GAAP income; evaluations and judgments regarding market position, balance sheet, runway, momentum, reinvestments, shareholder value, acquisition strategies, and synergies related to and the performance of acquired businesses (including Inform Diagnostics), investments and partnerships, relationships and the Company's testing services and technology; future growth and the Company's testing services and technologies; the Company's identification and evaluation of opportunities and its ability to capitalize on opportunities, capture market share, or to expand its presence in certain markets; and the Company's ability to continue to grow its business.

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 ongoing impacts of the COVID-19 pandemic, including the preventive public health measures that may continue to impact demand for its tests and the pandemic's effects on the global supply chain; the market potential for, and the rate and degree of market adoption of, the Company's tests, including its tests for COVID-19 and genetic testing generally; the Company's ability to capture a sizable share of the developing market for genetic and COVID-19 testing and to compete successfully in these markets, including its ability to continue to develop new tests that are attractive to its various customer markets, 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, particularly as the Company makes investments across its business; 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; 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 ability to grow and diversify its customer base and increase demand from existing and new customers; 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, strategic investments, joint

ventures, acquisitions, 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 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, as well as its results of operations for the periods covered by the financial results included in this press release.

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[1] Lin N, Lin Y, Xu J, et al. A multi-analyte cell-free DNA–based blood test for early detection of hepatocellular carcinoma. *Hepatol Commun*. 2022;00:1–11. doi:10.1002/hep4.1918.

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