HelioLiver™, an Innovative Liquid Biopsy Test for the Early Detection of Liver Cancer, is Now Commercially Available

December 6, 2021

HelioLiver can detect liver cancer in the earliest stages with a simple, non-invasive blood draw

HelioLiver is now available for patients through a provider order

IRVINE & TEMPLE CITY, Calif.--(BUSINESS WIRE)--Dec. 6, 2021-- Helio Health ("Helio") and its commercial partner, Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent"), today announced the commercial launch of HelioLiver™, 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. HelioLiver can detect HCC at its earliest stages when lesions are still very small, an area where traditional standard-of-care imaging tools often fall short, with the potential to enable more curative treatment options known to increase five-year survival rates by up to 13 times compared to when cancer has metastasized.[1,2]

Recent data presented at The Liver Meeting® 2021 outlined HelioLiver's superior sensitivity over currently available blood-based tests. With a specificity of 91%, HelioLiver demonstrated 76% sensitivity in detecting early-stage HCC, significantly outperforming other detection tools such as AFP (57%), GALAD (65%), and ultrasound (47%).[3,4]

"We are excited to offer patients at high risk of developing liver cancer a convenient and sensitive serial testing option to catch cancer early when it counts the most," said Justin Chen Li, U.S. Chief Executive Officer, Helio Health. "We are proud to partner with Fulgent to launch this innovative, simple, and reliable test that has the potential to redefine the future of cancer testing and foster better patient outcomes."

HelioLiver offers a simplified process for patients with a blood draw that can be conducted during a routine check-up, providing a quick and accurate way to receive regular surveillance for people at risk of developing liver cancer. While the American Association for the Study of Liver Diseases (AASLD) guidelines recommend ultrasound screening every six months for patients who are at risk, studies have shown that as few as 20% of patients actually receive regular surveillance due to the inconvenience of accessing testing via ultrasound.[5] Helio believes this number can dramatically increase with this new, blood-based test.

"Through our partnership with Helio, our joint priority is to bring HelioLiver to providers and patients in a seamless manner," said Brandon Perthuis, Chief Commercial Officer, Fulgent Genetics. "Leveraging our extensive commercial infrastructure, we are well-positioned to deliver an easy ordering experience for providers with our representatives at the ready to provide the best-in-class white glove service throughout the entire experience."

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

For more information about HelioLiver and its clinical performance, please visit www.HelioLiver.com.

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's 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 with its technology platform, Fulgent 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 our business is our 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 lab services.

About Helio Health

Helio Health 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.

Building on a robust research and development program, and with access to thousands of patient samples, the company is currently in clinical trials in the US and China with its lead liver cancer detection test. Helio's development program is focused on liver, colon, breast and lung cancer.

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

About Helio Health and Fulgent Genetics Partnership

In August 2021, Helio Health and Fulgent Genetics entered in a strategic partnership to co-brand and commercialize HelioLiver, a cell-free DNA (cfDNA) methylation blood test that incorporates protein markers and demographics for the detection of hepatocellular carcinoma (HCC) – or liver cancer. Fulgent will be responsible for laboratory operations, supply chain operations, marketing and sales leveraging its operational excellence and significant market reach, initially focused in the U.S. and Canada. Helio will provide intellectual property and continued support across research and development, publication development, market access and sales, as well as reimbursement operations. Fulgent and Helio will also collaborate on the development of additional liquid biopsy tests for different types of cancer in the future.

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, statements regarding the effectiveness and clinical utility of HelioLiver, including any potential increase in survival rates and increase in surveillance, suggestions that previously observed data will be indicative of future experience and any judgements and evaluations of Fulgent's infrastructure or commercial capabilities. Forward-looking statements are statements other than historical facts and relate to future events or circumstances. They are based on management's current assumptions, expectations and beliefs concerning future developments and their potential effect. 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 tests and the pandemic's effects on the global supply chain, the market potential for, and the rate and degree of market adoption of, HelioLiver, Fulgent's investments in its infrastructure, including its sales organization and operational capabilities, Helio and Fulgent's compliance with the various evolving and complex laws and regulations applicable to their business and industry 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. This press release also contains estimates and other statistical data made by independent parties. These data and estimates involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

The forward-looking statements made in this press release speak only as of the date of this press release, and neither Helio nor Fulgent assumes any obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law. Fulgent's reports filed with the U.S. Securities and Exchange Commission ("SEC"), including its annual report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 8, 2021 and the other reports it files from time to time, including subsequently filed quarterly and current reports, are made available on Fulgent's website upon their filing with the SEC. These reports contain more information about Fulgent, its business and the risks affecting its business.

[1] Yu, N. C., Chaudhari, V., Raman, S. S., et al. CT and MRI improve detection of hepatocellular carcinoma, compared with ultrasound alone, in patients with cirrhosis. Clinical Gastroenterology and Hepatology. 2011;9(2):161-167.

[2] National Cancer Institute: Cancer Stat Facts – Liver and Intrahepatic Bile Duct Cancer. Available at: https://seer.cancer.gov/statfacts/html/livibd.html [accessed November 30, 2021]

[3] Lin N, Lin Y, Xu J, et al. A multi-analyte blood test for accurate and early detection of hepatocellular carcinoma. Poster presented at: *American Association for the Study of Liver Diseases – The Liver Meeting*; November 12-15, 2021; Virtual.

[4] Tzartzeva K, Obi J, Rich NE, et al. Surveillance Imaging and Alpha Fetoprotein for Early Detection of Hepatocellular Carcinoma in Patients With Cirrhosis: A Meta-analysis. *Gastroenterology*. 2018;154(6):1706-1718.e1. doi:10.1053/j.gastro.2018.01.064

[5] Wang C, Chen V, Vu V, et al. Poor adherence and low persistency rates for hepatocellular carcinoma surveillance in patients with chronic hepatitis B. *Medicine (Baltimore)*. 2016;95(35):e4744. doi:10.1097/MD.0000000000004744

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