



Heartflow Files for FDA Clearance of Next Generation Product Offering to Help Evaluate the Presence of Narrowings and Plaque in the Coronary Arteries

December 13, 2021

Advanced innovations leverage Heartflow's core AI technology and are critical additions to Heartflow's product portfolio for delivering complete cardiac care

REDWOOD CITY, Calif. – December 13, 2021 — Heartflow, Inc., the leader in revolutionizing precision heart care, today announced it has submitted a 510k premarket application to the U.S. Food and Drug Administration (FDA) to add advanced anatomic assessment and plaque evaluation to the Heartflow FFR_{CT} Analysis. The PreRead anatomic assessment will help identify the presence and location of narrowings or stenoses in the coronary arteries based on coronary computed tomography (CT) scans. The Heartflow Plaque technology will provide plaque volume and characterize the type of plaque present. By adding the anatomic assessment and plaque evaluation to the physiological information currently provided by the Heartflow Analysis, physicians will gain a more comprehensive understanding of a patient's coronary disease burden and support efficient risk stratification of patients who may be at high risk of death from a heart attack.

"Heartflow is committed to becoming an indispensable partner to physicians in delivering precision heart care by providing a broad portfolio of game-changing innovations that leverages our core deep learning technology," said John H. Stevens, MD, President, CEO and Co-Founder, Heartflow. "The FDA submission is an important step towards delivering a solution that we believe supports complete cardiovascular care by providing clinicians with advanced insights about anatomy, physiology and plaque for their patients with coronary artery disease."

PreRead is designed to provide a rich anatomic assessment of each coronary CT, that, when considered by physicians in conjunction with other patient clinical information, helps physicians to quickly identify where coronary disease is present and understand the severity of the narrowing. The PreRead assessment highlights areas of modeled stenosis greater than 30% for vessels 1.8 mm or larger in diameter. This information will be provided as a 2D image of the coronary arteries, with areas of concern color coded by severity. In addition, CT images of each of the three main arteries are provided so physicians can more easily confirm the PreRead color-coded narrowings.

The PreRead assessment is intended to support clinical workflow efficiency, diagnostic accuracy and CT reader consistency as measured by repeatability and reproducibility. In an internal study, the PreRead assessment was 35% more repeatable and 47% more reproducible in classifying percent stenosis than expert CT readers' (Level 3) classification of the same cases. [1](#)

In addition, the Heartflow Plaque feature is based on a fully automated deep-learning (a form of AI) algorithm for characterizing and quantifying plaque. In an internal study, the Heartflow Plaque technology was found to be more reliable than expert CT readers in identifying different types of plaque and quantifying total plaque volume. [2](#)

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About the Heartflow FFR_{CT} Analysis

Starting with a standard coronary CT scan, the Heartflow Analysis leverages algorithms trained using deep learning and highly trained analysts to create a digital, personalized 3D model of the heart. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and provides FFR_{CT} values along the coronary arteries. This information is used by physicians in evaluating the impact a blockage may be having on blood flow and determine the optimal course of treatment for each patient. A positive FFR_{CT} value (≤ 0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

Data demonstrating the safety, efficacy and cost-effectiveness of the Heartflow Analysis have been published in more than 500 peer-reviewed publications, including long-term data out to five years. The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test. [3](#) To date, clinicians around the world have used the Heartflow Analysis for more than 100,000 patients to aid in the diagnosis of heart disease.

About Heartflow

Heartflow is the leader in revolutionizing precision heart care, uniquely combining human ingenuity with advanced technology. Heartflow's non-invasive Heartflow FFR_{CT} Analysis leverages artificial intelligence to create a personalized three-dimensional

model of the heart. Clinicians can use this model to evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Heartflow's technology is reflective of our Silicon Valley roots and incorporates over two decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, UK, Canada, Europe and Japan. For more information, visit www.Heartflow.com.

Important Information about the Business Combination and Where to Find It

In connection with the proposed Business Combination contemplated by the business combination agreement, dated as of July 15, 2021 (as amended, the "Business Combination Agreement"), by and among Longview Acquisition Corp. II ("Longview"), HF Halo Merger Sub, Inc. and Heartflow Holding, Inc., the parent company of Heartflow, Inc., Longview has filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 (the "Registration Statement"), which includes a preliminary proxy statement/prospectus and, as amended, will include a definitive proxy statement/prospectus, and certain other related documents, which will be both the proxy statement to be distributed to holders of shares of Longview's common stock in connection with Longview's solicitation of proxies for the vote by Longview's stockholders with respect to the Business Combination and other matters as may be described in the Registration Statement, as well as the prospectus relating to the offer and sale of the securities of Longview to be issued in the Business Combination. **Longview's stockholders and other interested persons are advised to read the preliminary proxy statement/prospectus included in the Registration Statement and the amendments thereto and the definitive proxy statement/prospectus, as well as other documents filed with the SEC in connection with the proposed Business Combination, as these materials will contain important information about the parties to the Business Combination Agreement, Longview and the proposed Business Combination.** After the Registration Statement is declared effective, the definitive proxy statement/prospectus and other relevant materials for the proposed Business Combination will be mailed to stockholders of Longview as of a record date to be established for voting on the proposed Business Combination and other matters as may be described in the Registration Statement. Stockholders will also be able to obtain copies of the preliminary proxy statement/prospectus, the definitive proxy statement/prospectus, and other documents filed with the SEC that will be incorporated by reference therein, without charge, once available, at the SEC's web site at www.sec.gov, or by directing a request to: Longview Acquisition Corp. II, 767 Fifth Avenue, 44th Floor, New York, NY 10153, Attention: Mark Horowitz, Chief Financial Officer or to info@longviewacquisition.com.

Participants in the Solicitation

Longview and its directors and executive officers may be deemed participants in the solicitation of proxies from Longview's stockholders with respect to the Business Combination. A list of the names of those directors and executive officers and a description of their interests in Longview is contained in the Registration Statement for the Business Combination and is available free of charge at the SEC's web site at www.sec.gov, or by directing a request to Longview Acquisition Corp. II, 767 Fifth Avenue, 44th Floor, New York, NY 10153, Attention: Mark Horowitz, Chief Financial Officer or to info@longviewacquisition.com. Additional information regarding the interests of such participants is contained in the Registration Statement.

Heartflow and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of Longview in connection with the Business Combination. A list of the names of such directors and executive officers and information regarding their interests in the Business Combination is contained in the Registration Statement.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Heartflow's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "indicate," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, Heartflow's statements regarding the PreRead assessment, its expected features and capabilities and Heartflow's application for FDA clearance of the new product offering. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside Longview's and Heartflow's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: (1) the ability of Longview and Heartflow prior to the Business Combination, and the combined company following the Business Combination, to meet the closing conditions in the Business Combination Agreement, including due to failure to obtain approval of the stockholders of Longview and Heartflow or certain regulatory approvals, or failure to satisfy other conditions to closing in the Business Combination Agreement; (2) the occurrence of any event, change or other circumstances, including the outcome of any legal proceedings that may be instituted against Longview and Heartflow following the announcement of the Business Combination Agreement and the transactions contemplated therein, that could give rise to the termination of the Business Combination Agreement or could otherwise cause the transactions contemplated therein to fail to close; (3) the inability to obtain or maintain a stock exchange listing of the combined company's Class A common stock, as applicable, following the Business Combination; (4) the risk that the Business Combination disrupts current plans and operations as a result of the announcement and consummation of the Business Combination; (5) the inability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition and the ability of the combined company to grow and manage growth profitably and retain its key employees; (6) costs related to the Business Combination; (7) changes in applicable laws or regulations or the healthcare industry; (8) the inability

of the combined company to raise financing in the future; (9) the success, cost and timing of Heartflow's and the combined company's product development activities, including market adoption of their current and future products; (10) the inability of Heartflow or the combined company to obtain and maintain regulatory approval for their current and future products, and any related restrictions and limitations of any approved product; (11) the inability of Heartflow or the combined company to build effective sales and marketing capabilities to support the combined company's growth strategy; (12) the inability of Heartflow or the combined company to maintain Heartflow's existing customer, license, and collaboration agreements, and arrangements with commercial and government payers; (13) future changes in clinical guidelines, or the timing of increased adoption and use, if any, of Heartflow's products as a result of the publication of positive clinical guidelines that support the use of Heartflow's and the combined company's products; (14) the inability of Heartflow or the combined company to compete with other companies marketing or engaged in the development of products that aid physicians in the evaluation and treatment of coronary artery disease; (15) the size and growth potential of the markets for Heartflow's and the combined company's products, and each of their ability to serve those markets, either alone or in partnership with others; (16) the pricing of Heartflow's and the combined company's products and reimbursement for medical procedures conducted using Heartflow's and the combined company's products, including future changes to or reductions in reimbursement and payment rates; (17) Heartflow's and the combined company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; (18) Heartflow's and the combined company's financial performance; (19) the impact of COVID-19 on Heartflow's business and/or the ability of the parties to complete the Business Combination; and (20) other risks and uncertainties indicated from time to time in the proxy statement/prospectus relating to the Business Combination, including those under "Risk Factors" in the Registration Statement, and in Longview's other filings with the SEC.

The foregoing list of factors is not exclusive, and investors should not place undue reliance upon any forward-looking statements, which speak only as of the date made. Neither Heartflow nor Longview undertakes or accepts any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in their expectations or any change in events, conditions or circumstances on which any such statement is based.

No Offer or Solicitation

This communication shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Business Combination. This communication shall also not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of section 10 of the Securities Act of 1933, as amended.

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1. Heartflow Internal Study. Results based on Modified CADRADs. December 2021
 2. Heartflow Internal Study. December 2021
 3. Driessen, R., et al. J Am Coll Cardiol. 2019;73(2),161-73