Hyperfine, Inc. Announces FDA Clearance for Improved AI-Powered Software and Expanded Field of View for the Swoop® Portable MR Imaging® System

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Latest Swoop® software improves image quality for DWI imaging of the brain

GUILFORD, Conn., Feb. 13, 2023 (GLOBE NEWSWIRE) -- Hyperfine, Inc., the groundbreaking medical device company that created the Swoop® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) device for imaging of the brain, today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance and launch of the company's upgraded AI-powered software.

The most recently cleared Swoop® software improves the image quality of the diffusion-weighting imaging (DWI) sequence with increases in its signal-to-noise ratio. An additional update in this software release increases the Swoop® Portable MR Imaging® System field of view by 10% for T1, T2, and FLAIR sequences to match the previously improved DWI sequence's 20cm field of view. Field of view size is important for visualizing pathology deep in the brain.

"The latest Swoop® software improves image quality with notable improvement in the appearance of the DWI images. The improved image quality more clearly displays underlying brain structure, further accentuating diffusion positivity and potentially increasing confidence in image interpretation and clinical decision-making," said Edmond Knopp, M.D., senior medical director of Hyperfine, Inc.

"Our team continues to make rapid and significant software advancements for our first-in-class ultra-low-field Swoop® Portable MR Imaging® System to deliver diagnostic-quality brain images that enable timely clinical decision-making at the point of care," said Maria Sainz, president and CEO of Hyperfine, Inc. "We are committed to continuous improvement to optimize the clinical utility of the Swoop® system while driving commercial adoption across leading institutions globally. We have released two new sequences (T1 Standard and Fast T2) in the last twelve months, improved DWI sequence image quality twice, and expanded the system's field for view."

Hyperfine, Inc. first received initial FDA clearance for the Swoop® Portable MR Imaging® System in 2020 and has received two additional FDA clearances for hardware improvements and seven clearances for upgraded software, including BrainInsight™ software—with five of these clearances received in 2022. Hyperfine, Inc. maintains a total installed base* of 100 Swoop® systems globally, and twenty peer-reviewed clinical publications have included Swoop® system data.

"We're investing heavily in software development, AI, and image quality and are committed to expanding the toolbox available to our users," said Tom Teisseyre, chief product officer of Hyperfine, Inc. "These initiatives are core to our transformative approach to MR imaging, making it a reality for a growing number of patients in the fast-evolving diversity of sites of care."

For more information about the Hyperfine, Inc. Swoop® Portable MR Imaging® System, please visit http://www.hyperfine.io.

*As of Hyperfine, Inc.'s third-quarter 2022 earnings report on November 10, 2022. The Swoop® system total installed base consists of commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations. The Swoop® system total installed base (or total installed units) is the number of Swoop® devices deployed to hospitals, other healthcare providers, and research institutions. We view the total installed base as a key metric of the growth of our business and is measured from period over period.

About Hyperfine, Inc. and the Swoop® Portable MR Imaging® System

Hyperfine, Inc. (NASDAQ: HYPR) is the groundbreaking medical technology company that created the Swoop® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) system capable of providing neuroimaging at the point of care. The Swoop® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The Swoop® system has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, and is also available in New Zealand and Pakistan.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging, and data solutions. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the Swoop® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. Traditionally, access to costly, stationary, conventional MRI technology can be inconvenient or not available when needed most. With the portable, ultra-low-field Swoop® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit hyperfine.io.

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. Hyperfine, Inc. ("Company", or "the Company")'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," "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, expectations about the Company's financial and operating results, the benefits of Company's products and services, and

Company's future performance and its ability to implement its strategy. 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 of Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of Company product development and commercialization activities, including the degree that the Swoop® system is accepted and used by healthcare professionals; the impact of COVID-19 on Company business; the inability to maintain the listing of Company's Class A common stock on the Nasdaq; the inability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition and Company's ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of Company to raise financing in the future; the inability of Company. to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of Company to identify, in-license or acquire additional technology; the inability of Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of Company to compete with other companies currently marketing or engaged in the development of products and services that Company is currently marketing or developing; the size and growth potential of the markets for Company's products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of Company's products and services and reimbursement for medical procedures conducted using Company's products and services; Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing; Company's financial performance; and other risks and uncertainties indicated from time to time in Company's filings with the Securities and Exchange Commission, including those under "Risk Factors" therein. Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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