Hyperfine Announces Extensive Clinical Study Coverage at RSNA 2024, Showcasing the Body of Evidence Supporting the Use of the Swoop® System Across Different Sites of Care

December 5, 2024

Eleven clinical studies presented at RSNA 2024 highlighted the growing clinician experience with the Swoop® system for imaging diverse patient groups in emergency departments and neuro ICUs.

GUILFORD, Conn.--(BUSINESS WIRE)--Dec. 5, 2024-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable magnetic resonance (MR) brain imaging system—the Swoop® system—today highlighted data and conclusions presented at the Radiological Society of North America (RSNA) 2024 Annual Meeting in Chicago. Contributions from eleven leading institutions—early adopters of point-of-care MR brain imaging technology—underscore the increasing utility of AI-powered portable MR imaging and the growing physician experience with its application, particularly for acute stroke diagnosis.

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The Swoop® Portable MR Imaging® System (Photo: Business Wire)

The clinical studies presented clinician experience using Swoop® system images for intracerebral hemorrhage monitoring, acute ischemic stroke detection, and advanced imaging techniques for multiple sclerosis. These studies highlighted the potential of the Swoop® system to expand access to critical diagnostic imaging for acute ischemic stroke and other neurological conditions, providing actionable insights where conventional high-field MRI may not be viable.

A team from Washington University School of Medicine in St. Louis, a leading center in AI-powered portable MR imaging utilization, showcased their experience with a presentation that marks the most extensive study to date using the Swoop® system, including data from over 350 exams in acute neurological care settings. In an abstract titled *Application of clinical low field mobile MRI in a large academic medical center*, neuroradiologists evaluated how Swoop® system images compare to conventional MRI (1.5T or 3T) in helping physicians identify brain pathologies. The study concludes that point-of-care low-field portable MR carries promise for rapid delivery of actionable diagnostic imaging to persons with acute neurological injury and should be considered for patients with acute stroke who cannot readily undergo conventional MRI.

One of the authors, Cyrus A. Raji, MD, PhD, commented, "Our experience with the portable MR imaging system has shown it to be a valuable addition to acute neurological care in our facility. It allows for follow-up of large strokes and intracranial hemorrhage in the neurocritical ICU without the need for transfer of acutely ill patients to the MRI suites."

In another study, Dr. Nandor Pinter of the Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo presented data from the prospective, international, multi-site ACTION PMR (Acute Ischemic Stroke Detection with Portable MR) study. Massachusetts General Brigham and Ohio State Hospitals also participated in this study, which evaluated the accuracy of images acquired with AI-powered portable MRI in detecting acute ischemic stroke. The presentation, titled *Acute stroke detection using portable ultra low-field MRI: A multicenter outlook*, demonstrated that images from the Swoop® system showed lesions and location identification capability. The authors concluded that low-field MR imaging has the potential to enable physicians to detect hyperacute stroke, which may increase access to MRI given its unique portable capabilities.

"The ACTION PMR study looked at stroke detection using Swoop® system images compared to high-field MRI and CT, and our interim findings highlight the promising role of AI-powered portable MRI in acute stroke care," said Dr. Nandor Pinter, research assistant professor in the Department of Neurosurgery at the University at Buffalo. "Our conclusions, using the Swoop® system in the ED across four institutions, show the system's potential to revolutionize hyperacute stroke workflow and diagnostics."

"The eleven abstracts presented at RSNA this week not only demonstrate the Swoop® system's ability to deliver diagnostic-quality MR brain imaging at the point of care but also reflect the growing excitement and momentum around portable MRI technology," said Dr. Edmond Knopp, Chief Medical Officer at Hyperfine. "These results expand the evidence base for stroke applications, showcasing the system's potential to transform care in resource-limited and high-acuity settings. The enthusiasm we've seen from clinicians and researchers at RSNA underscores the Swoop® system's impact in advancing stroke diagnostics and improving patient outcomes when and where it's needed most."

For more information about the Swoop® Portable MR Imaging® system, please visit hyperfine.io.

About the Swoop® Portable MR Imaging® System

The Swoop® Portable MR Imaging® system is U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. It is a portable, ultra-low-field 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 also has CE certification in the European Union and UKCA certification in the United Kingdom. The Swoop® system is commercially available in a select number of international markets.

About Hyperfine, Inc.

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of professional care. The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging. 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. For more information, visit hyperfine.io.

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This press release includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the “Company”) 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, the Company’s goals and commercial plans, the benefits of the Company’s products and services, and the 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 the 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 the Company’s 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 the Company’s business; the inability to maintain the listing of the Company’s Class A common stock on the Nasdaq; the Company’s inability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability of the 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 the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently marketing or developing; the size and growth potential of the markets for the Company’s products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company’s products and services and reimbursement for medical procedures conducted using the Company’s products and services; the Company’s estimates regarding expenses, revenue, capital requirements and needs for additional financing; the 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. The 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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