Hyperfine Announces Promising Interim Findings on the Value of Portable, Ultra-low-field MR Imaging for Acute Stroke Care

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The Swoop® Portable MR Imaging® system shows faster time-to-scan compared to conventional MRI and good specificity in emergency stroke care

PARIS--(BUSINESS WIRE)--Sep. 23, 2024-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared portable magnetic resonance (MR) brain imaging system—the Swoop® system—today announced the presentation of interim data supporting the role portable ultra-low-field MRI can play in acute stroke workup in a hospital emergency department setting.

The findings from the study, titled *Interim Analysis from Single Centre Observational Study of Ultra-Low Field Portable MRI in Acute Stroke Diagnostic Workup,* were presented by Keith Muir, MD, of the University of Glasgow, during a scientific session at the 2024 European Society of Neuroradiology (ESNR) Annual Meeting.

This study, which includes a subset of patients from phase one of the prospective, international, multi-site ACTION PMR (Acute Ischemic Stroke Detection with Portable MR) study, analyzed images from the ultra-low-field Swoop® MR brain imaging system to assess the system's performance in acute care stroke workup as compared to the current standard of care. The analysis compared time-to-scan, diagnostic performance, specificity, and patient experience between ultra-low-field MRI, conventional MRI, and head CT.

Key findings showed that the Swoop® system was dramatically faster than conventional MRI, with a median time-to-scan of 2.5 hours compared to 27.7 hours. The data also demonstrated reliability in acute stroke diagnosis with comparable diagnostic performance compared to head CT and good specificity when compared to routine clinical MRI (1.5T). Further, nearly all patients reported a positive experience with the Swoop® system.

The conclusion states, "This interim analysis demonstrates that the portable [ultra-low-field] MRI system is a promising tool for the acute stroke diagnostic workup in an emergency department setting. The improved time to imaging compared to routine MRI could facilitate quicker decision-making in acute stroke management. Additionally, the high tolerance rate among patients underscores its potential usability in a clinical environment. The findings suggest that portable [ultra-low-field] MRI could enhance stroke diagnosis accessibility and efficiency, particularly in settings where conventional MRI availability is limited."

Dr. Edmond Knopp, Vice President of Medical Affairs at Hyperfine, commented, "Being at ESNR in Paris this year and showcasing our Swoop® system, we witnessed the growing interest and enthusiasm across the European neuroradiology community. This excitement was most notable when the attendees had the opportunity to see the system up close and personal. We were very pleased with Dr. Muir and his team's participation in the ACTION PMR stroke study, and it was great to have Dr. Muir share exceptional data acquired during the study. Their findings highlight the potential of the Swoop® system's clinical impact in improving stroke diagnosis and treatment."

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.

Hyperfine, Swoop, and Portable MR Imaging are registered trademarks of Hyperfine, Inc.

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. 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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