Hyperfine Announces Publication of Breakthrough Clinical Data Demonstrating the Swoop® System's Enhanced Stroke Detection Capabilities

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The largest dataset to date on stroke detection with the Swoop® system demonstrates the ability to identify small strokes rapidly and reliably, reinforcing its clinical value for acute care and emergency settings.

GUILFORD, Conn.--(BUSINESS WIRE)--Jan. 27, 2026-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable MRI system for the brain—the Swoop® system—today announced results from the largest data set to date evaluating stroke detection with the Swoop® system. This data provides strong evidence supporting the use of AI-powered portable MRI for stroke detection in multiple clinical settings, including the emergency department.

The prospective multi-center observational study, published in the November issue of Stroke: Vascular and Interventional Neurology (SVIN), evaluates 95 patients, combining data from the ACTION PMR study at Massachusetts General Hospital and Buffalo General Medical Center, with data from Yale New Haven Hospital. The study evaluated the sensitivity and specificity of ischemic lesion detection, comparing both the original and next-generation Swoop® system scanners, along with a comparison of two types of DWI sequences, a sequence that is critical for stroke detection.

The advanced multi-directional DWI sequence on the next-generation Swoop® system achieved dramatic improvements in diagnostic performance over the original scanner:

- **Enhanced Detection of Small Lesions:** Successfully identified lesions as small as 2.8 mm (0.15 mL), enabling detection of very small strokes
- **Perfect Accuracy for Clinically Relevant Lesions:** Achieved 100% sensitivity and 100% specificity for lesions greater than 1.0 mL.
- **Improved Efficiency:** Reduced scan time by approximately 30%, making stroke imaging feasible in time-critical emergency settings
- **Superior Image Quality:** Demonstrated improved image uniformity across the brain, enhancing diagnostic confidence

"We previously showed that using DWI in combination with FLAIR on the portable MRI system can be used as a 'tissue clock' for stroke detection, similar to conventional MRI. With this study, we took the next step and evaluated the capability of ultra-low-field MRI with advanced, multi-directional DWI sequences to detect very small ischemic lesions," said Taylor Kimberly, MD, PhD, Chief of the Neurocritical Care Division at Mass General Brigham. "The results show that the next-generation portable MRI system with a multi-directional DWI sequence enables detection of very small strokes in a clinically feasible timeframe. The portable MRI system's ability to detect clinically relevant strokes opens new possibilities for transforming stroke diagnosis and management—bringing timely evaluation to more patients and care settings than ever before."

"Stroke detection represents a critical driver of the Swoop® system's expansion into emergency departments," commented Maria Sainz, President and CEO of Hyperfine. "The results from our next-generation Swoop® system, combined with our new, advanced multi-direction DWI sequence that was recently cleared by the FDA, are truly remarkable. This data gives us even greater confidence that the Swoop® system can reliably detect clinically relevant strokes, streamline workflows, and further strengthen the value of integrating portable MRI into stroke diagnosis and care."

Hyperfine provided portable MRI systems as part of sponsored research agreements. The company was not involved in the design or analysis of this investigator-initiated study, nor in the publication decision.

For more information about the Swoop® system, please visit HyperfineMRI.com.

About the Swoop® Portable MRI Systems
The Swoop® Portable MR Imaging® Systems are U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. They are portable, ultra-low-field magnetic resonance imaging devices 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.

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 HyperfineMRI.com.

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, including its entrance into new markets. 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 inability to maintain the listing of the Company's Class A common stock on the Nasdaq Stock Market; 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 progress on product advancements and improvements; 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; anticipated National Institutes of Health funding pressures; the effect of U.S. export controls and tariffs; 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 the 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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