Hyperfine Announces Enrollment of First Patient in Study to Expand Intended Use of the Swoop® System with Contrast Agents

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The prospective study is designed to evaluate the feasibility and visualization benefits of contrast-enhanced ultra-low-field portable MRI to support an FDA 510(k) submission.

GUILFORD, Conn.--(BUSINESS WIRE)--Jan. 15, 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 the enrollment of the first patient in the Contrast PMR study, a prospective, multi-center clinical study designed to evaluate the feasibility and visualization benefits of contrast-enhanced ultra-low-field portable MRI. The study is intended to support a future FDA submission to expand the Swoop® system's intended use to include gadolinium-based contrast agents, potentially unlocking new applications across multiple care settings.

The primary objective of the study is to evaluate the visualization of brain lesions, including lesions associated with blood-brain barrier disruption, using contrast agents with ultra-low-field portable MRI. Visualization benefits will be assessed using three endpoints related to lesion appearance. The study will enroll approximately 70 patients across multiple sites in the United States.

"Portable MRI has already changed how and where we image the brain at our center, and incorporating the use of contrast is a natural next step," said Mark Anderson, MD, Chief Medical Officer at the CHRISTUS Mother Frances Hospital study site. "Contrast-enhanced MRI is important for evaluating many neurological conditions, and we are looking forward to participating in this study to assess contrast-enhanced imaging with the Swoop® system. This could further expand Swoop® system utility and transform how we diagnose and monitor brain conditions."

"Seeing contrast at ultra-low field strengths is an exciting expansion opportunity for the utility of the Swoop® system. The ability to use gadolinium-based contrast agents could enhance its clinical utility, particularly in cases where contrast is commonly used, such as brain tumors, suspected abscesses, and inflammatory conditions like multiple sclerosis. With the Contrast PMR study enrolling, we anticipate submission to the FDA for indication expansion towards the end of 2026," said Tom Teisseyre, PhD, Chief Operating Officer at Hyperfine.

Additional details about the study are available at ClinicalTrials.gov (NCT07296263).

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. 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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