Hyperfine Announces Completion of Enrollment in the Contrast PMR Study to Support the Submission to Expand Indications for Use of the Swoop® System with Contrast Agents

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The anticipated indication expansion would position Hyperfine to drive adoption in outpatient neurology and establish new opportunities for portable MRI in post-procedural imaging in operating room workflows.

GUILFORD, Conn.--(BUSINESS WIRE)--Sep. 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 that it has completed enrollment of 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 using the Swoop system. The study is intended to support the first expansion of the Swoop system's indications for use since its original FDA clearance and represents an important step toward broadening the clinical utility of portable MRI.

Contrast-enhanced MRI represents a meaningful portion of brain MRI examinations performed today and plays a critical role in the evaluation of brain tumors, inflammatory disorders, and other conditions associated with blood-brain barrier disruption. The primary objective of the Contrast PMR study is to evaluate the visualization of brain lesions, including those associated with blood-brain barrier disruption, using contrast agents with ultra-low-field portable MRI. Visualization is assessed across three endpoints related to lesion appearance, with the study specifically evaluating the Swoop system's ability to visualize common contrast-enhancing brain lesions using commonly administered gadolinium-based contrast agents.

"The completion of enrollment of the Contrast PMR study is an important milestone in expanding the use of portable MRI across clinically relevant imaging modalities across a broader range of neurological applications," said W. Taylor Kimberly, MD, PhD, Chief, Division of Neurocritical Care, Neurology, Mass General Brigham. "Contrast-enhanced imaging is fundamental to the evaluation of many brain lesions, including tumors and other conditions associated with blood-brain barrier disruption. This study is designed to assess whether portable MRI can provide meaningful visualization of the types of lesions neurologists and neurosurgeons routinely evaluate using contrast-enhanced MRI. If successful, contrast-enhanced portable MRI could meaningfully expand the role of point-of-care imaging across a wide range of clinical settings."

"We believe contrast-enhanced imaging can be a powerful catalyst for expanding adoption of the Swoop system and extending its value across the diverse care settings we serve," said Maria Sainz, President and Chief Executive Officer of Hyperfine. "In addition to supporting critical diagnostic and treatment decisions across a broad range of clinical settings, contrast-enhanced brain imaging benefits from established dedicated reimbursement pathways, creating a strong foundation for adoption and long-term value for providers. We see this unlocking expanded use in outpatient settings and opening new applications for post-procedural imaging in surgical environments, including assessment of residual tumor after resection. I want to congratulate the Hyperfine team and our clinical collaborators on completing enrollment in this study as an important milestone in pursuit of an indication expansion for the Swoop system to include contrast-enhanced brain imaging, broadening its clinical utility

Following completion of enrollment, Hyperfine will proceed with image review, data analysis, and preparation of a planned FDA 510(k) submission, which the company plans to submit by the end of 2026. FDA clearance for the use of contrast would represent the first expansion of the Swoop system's indications for use since its original FDA clearance.

Additional information about the study is available through ClinicalTrials.gov (NCT07296263). The expanded use of the Swoop system with contrast agents remains subject to FDA clearance.

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.

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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 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; existing and potential future National Institutes of Health funding pressures; existing and potential future effects from 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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