HYPERFINE

Hyperfine Enrolls Initial Patients in NEURO PMR Study to Evaluate Use of AI-Powered Portable MRI in Neurology Offices

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Real-world study will assess clinical utility and patient experience across diverse neurological conditions to support adoption of AI-powered portable MRI systems in the office setting.

GUILFORD, Conn.--(BUSINESS WIRE)--Apr. 15, 2025-- 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, first approved in 2021—today announced the enrollment of initial patients in the NEURO PMR (Neurological Evaluation in the Office with Portable MRI) study.

The **NEURO PMR study** is the first multi-center, prospective observational study of its kind, comparing portable ultra-low-field MRI and conventional high-field MRI with respect to pathology findings, clinical utility, and patient experience. Conducted with two premier private neurology practices—the **DENT Neurologic Institute** and **Texas Neurology** —the study utilizes the latest AI-powered portable MRI technology with advanced image quality. The study has a target enrollment of 100 patients and is expected to conclude by year-end.

“Neuroimaging has become a cornerstone of modern neurological care, with neurologists ordering an average of 500 MRIs each year. Yet, in-office imaging remains out of reach for most private practices,” explained Dr. Laszlo Mechtler, Principal Investigator of the study and Chief Medical Officer at the DENT Neurologic Institute. “This study aims to identify the best uses for portable brain MRI technology in a comprehensive neurology practice. The goal is to make advanced imaging more accessible, affordable, and convenient for both patients and healthcare providers.”

The Hyperfine AI-powered portable MRI system removes many of the barriers that have made conventional high-field MRI systems inaccessible for placement in neurology offices. Unlike conventional MRI systems, portable MRI doesn’t require costly siting, helium, or specialized MRI technologists to operate. With its simple plug-and-play design, the system enables on-demand brain imaging directly in the exam room. Furthermore, as of November 2024, IAC Accredited medical offices that use portable MRI systems qualify for reimbursement through the Centers for Medicare and Medicaid Services (CMS).

"As more healthcare moves to outpatient settings, patients increasingly expect neurology practices to offer both diagnostic and treatment services under one roof," adds Dr. Gincy Samuel, site Principal Investigator at Texas Neurology. "Portable MR technology aligns well with this trend, offering enhanced care and convenience in a single location—a shift we believe will only gain momentum. It provides a vital clinical function for centers that would not normally have immediate access to imaging, especially in underserved, rural, and community centers."

The NEURO PMR study is a key initiative in the Hyperfine office market entry strategy. It represents a significant step forward in making advanced imaging available to neurology practices of all sizes, ultimately reducing healthcare costs while improving patient access and clinical outcomes.

For more information about Hyperfine and AI-powered portable MRI technology, please visit hyperfine.io.

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, AI-powered, 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 and continue to improve 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.

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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