

Portable MRI as a Tissue Clock for Acute Ischemic Stroke: Multi-Site Study to be Published in August 2024 Edition of Annals of Neurology Shows the Value of the Ultra-Low-Field Swoop® Portable MR Imaging® System in Acute Stroke Diagnosis

July 15, 2024

The publication includes a subset of data from the ACTION PMR stroke study and provides early evidence that the Swoop[®] system is a promising tool for enabling critical stroke treatment choices in urgent care settings.

GUILFORD, Conn.--(BUSINESS WIRE)--Jul. 15, 2024-- Hyperfine (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 Swoo® system—today highlights the results from a multi-site observational study that showed the value of using Swoop® system images to quickly assess stroke patients and help guide physicians making critical treatment decisions. This publication marks the first to include a subset of ACTION PMR study data and shows encouraging results.

The study, entitled "Diffusion-Weighted Imaging and Fluid-Attenuated Inversion Recovery Mismatch on Portable, Low-Field Magnetic Resonance Imaging Among Acute Stroke Patients," will be published in the August 2024 issue of the Annals of Neurology. It included 71 patients and was conducted by a team from several institutions, including Massachusetts General Hospital and the University at Buffalo, two of the centers in the ACTION PMR study.

"Our goal is to assess whether portable, ultra-low-field MRI can be used as a tissue clock to characterize acute stroke, which has the potential to inform treatments and improve outcomes. Thus far, we have convincing data on FLAIR showing that this is, in fact, the case," said Dr. Taylor Kimberly, Chief of the Division of Neurocritical Care at Massachusetts General Hospital, one of the lead authors.

"We would like to congratulate Dr. Kimberly and all the authors on this elegant study demonstrating the Swoop[®] system's utility in stroke management," said Edmond A. Knopp, MD, Hyperfine Vice President of Medical Affairs. "We eagerly await additional analysis of the entire ACTION PMR dataset, which we believe will show the benefit that Swoop[®] system images can bring to the overall care and management of patients presenting with symptoms of acute cerebral ischemic disease."

The Acute Ischemic Stroke Detection with Portable MR (ACTION PMR) study is a prospective, international, multi-site observational study that aims to examine the integration of brain imaging with the portable Swoop[®] system into the stroke diagnosis and treatment workflow. ACTION PMR has already enrolled over 100 patients at four institutions and is composed of a series of investigator-sponsored studies. The initial 100 patients allow for a direct comparison of stroke detection between ultra-low-field MRI, conventional high-field MRI, and CT as a means to assess the capability of stroke detection of the Swoop[®] system. The study will continue into a workflow phase starting later this year, evaluating the ease of access and versatility of using the Swoop[®] system in emergency departments and stroke centers within hospital networks.

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 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.

The Hyperfine logo, 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 Nasdag; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240715844168/en/

Media Contact

Shay Smith Health+Commerce shay@healthandcommerce.com

Investor Contact Marissa Bych Gilmartin Group LLC marissa@gilmartinir.com

Source: Hyperfine, Inc.