Hyperfine Announces Presentation of Initial Data from Observational Clinical Studies Evaluating the Use of Portable MR Brain Imaging for Alzheimer's Patients

July 30, 2024

Two poster presentations at AAIC provide early evidence of the value of ultra-low-field Swoop® system MR brain images in ARIA-E detection and morphography evaluation in patients with Alzheimer's disease

PHILADELPHIA--(BUSINESS WIRE)--Jul. 30, 2024-- Hyperfine, Inc. (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 Swoop® system—today announced the presentation of data using the Swoop system to image patients with Alzheimer's disease including initial data from the CARE PMR study. The data was presented at the 2024 Alzheimer's Association International Conference (AAIC) in Philadelphia from July 28 to August 1.

The CARE PMR (Capturing ARIA Risk Equitably with Portable MR) study is a collection of data from multiple sites assessing the clinical utility and workflow benefits of using Swoop® system images to detect amyloid-related imaging abnormalities (ARIA) in Alzheimer's patients receiving amyloid-targeting therapy. These investigator-initiated observational studies aim to provide insights into the potential of ultra-low-field, portable MR brain imaging to enhance care for patients with Alzheimer's disease across many sites of care.

At the conference, researchers from Washington University in St. Louis, a center actively enrolling patients in the CARE PMR study, presented a poster titled "Advanced Imaging Modalities for ARIA Detection and Treatment Efficacy Monitoring in Lecanemab Therapy for Alzheimer's Disease: A Collaborative Prospective Study." The poster, authored by Jude-Patrick Nnamdi Okafor, MD, *et al.*, reported data on sixteen patients. Notably, one participant exhibited "evidence of hyperintensity on FLAIR, consistent with ARIA-E," which was deemed "well detected at low field strength."

Researchers from Massachusetts General Hospital virtually presented a poster titled "Portable, Low-field MRI for Alzheimer's Disease," authored by W. Taylor Kimberly, MD, PhD, *et al.* This poster focused on the quantitative assessment of ultra-low-field MRI images compared to conventional high-field MR images in evaluating brain morphometry in Alzheimer's patients. The study highlighted a strong agreement in volumes between conventional high-field MR images and low-field MR images. The poster concluded, "Given its portability and low operational cost, [low-field] MRI holds promise as a valuable tool to diagnose [Alzheimer's disease] and monitor its progression."

Dr. Edmond Knopp, Vice President of Medical Affairs at Hyperfine, commented, "The impressive image quality achieved with our ultra-low-field MRI technology opens up the potential to provide critical diagnostic information for patients with Alzheimer's disease across many sites of care, including infusion centers and clinics that currently cannot offer on-site imaging capabilities. These posters provide early evidence that portable MRI could transform Alzheimer's disease management."

Access the abstracts through AAIC using the following links:

Title: Advanced Imaging Modalities for ARIA Detection and Treatment Efficacy Monitoring in Lecanemab Therapy for Alzheimer's Disease: A Collaborative Prospective Study
Authors: Jude-Patrick Nnamdi Okafor, MD, *et al*.

Title: Portable, Low-field MRI for Alzheimer's Disease
Authors: W. Taylor Kimberly MD PhD, *et al*.

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.

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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