Hyperfine, Inc. Launches Observational Study to Define New Imaging Paradigm in Stroke Care

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In addition to the study, the company appoints a world-class stroke advisory board as part of its acute ischemic stroke initiatives

GUILFORD, Conn.--(BUSINESS WIRE)--Jul. 11, 2023-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that created the *Swoop*® system, the world's first FDA-cleared portable magnetic resonance brain imaging system, has announced the commencement of an international, multi-site observational study, ACTION PMR (ACuTe Ischemic strOke detectioN with Portable MR). To support its acute stroke care initiatives, Hyperfine Inc. has formed an advisory board of world-renowned stroke experts.

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(Photo: Business Wire)

As a prospective, international, multi-site observational study, ACTION PMR aims to examine the integration of brain imaging with the *Swoop*® system into the stroke diagnosis and treatment workflow. The goal is to use point-of-care brain imaging to identify strokes and viable brain tissue that can be saved.

MRI scans, which are more precise than CT scans, are recommended for diagnosing acute ischemic stroke within twelve hours of symptom onset by the American Academy of Neuroradiology. However, the limited availability of MRI scanners near acute care settings in many hospitals highlights the need for point-of-care MR brain imaging.

"The ACTION PMR study has the potential to improve stroke treatment all over the world, with the *Swoop*® system assisting clinicians in imaging brain tissue and making timely diagnoses which could lead to the implementation of more effective treatments and help to facilitate better patient outcomes," says Dr. Khan Siddiqui, Hyperfine, Inc. Chief Medical Officer and Chief Strategy Officer.

Four investigators from leading institutions will lead the study: Dr. W. Taylor Kimberly of Massachusetts General Hospital, Dr. Adnan Siddiqui of the University at Buffalo, Dr. Vivien Lee of the Ohio State University Wexner Medical Center, and Dr. Keith Muir of the University of Glasgow.

"Refining stroke diagnosis and care is central to all we do; as such, our research will focus on patients who don't immediately qualify for thrombectomy," says Dr. Taylor Kimberly of Massachusetts General Hospital. "We hope this study may contribute to timelier diagnoses, paving the way for improved patient outcomes."

Alongside the ACTION PMR study, the newly formed stroke advisory board, comprised of experts in the field, will provide insights and experiences to guide and define the impact the *Swoop*® system can have in the fast-evolving field of acute stroke care.

Maria Sainz, Hyperfine, Inc. President and CEO, adds, "There is a significant unmet need in stroke imaging and workflow representing a very compelling incremental opportunity for Hyperfine, Inc. Our ambition is to enable innovative and readily accessible brain imaging solutions that enhance the chances of recovery for every patient. ACTION PMR is an important project for us, and we are honored to be working with our distinguished clinical investigators and stroke advisors to navigate the challenges and opportunities in stroke care and formulate the role the *Swoop*® system can play in acute stroke workflow."

For more information about the *Swoop*® *Portable MR Imaging*® system, please visit hyperfine.io.

About Hyperfine, Inc. and the *Swoop*® *Portable MR Imaging*® System

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking medical technology company that created the *Swoop*® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) system capable of providing brain imaging at the point of care. The *Swoop*® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where a 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 has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, CE certification in the European Union, and is also available in New Zealand.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging and data solutions. 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. Traditionally, access to costly, stationary, conventional MRI technology can be inconvenient or not available when needed most. With the portable, ultra-low-field *Swoop*® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit hyperfine.io.

Hyperfine, 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. Hyperfine, Inc. ("the Company")'s actual results 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 goals, the Company's 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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