Hyperfine, Inc. to Expand Global Market Reach with Appointment of International Distributors in Key European Markets

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- Distributors appointed in France, the United Kingdom, and Italy

- Industry veteran Enrico Barini joins as International Business Development Director

GUILFORD, Conn.--(BUSINESS WIRE)--May 10, 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 it has entered into agreements with three experienced and accomplished distributors to support commercial expansion plans of the Swoop® system into European markets with an initial focus on France, the United Kingdom, and Italy.

In 2023, Hyperfine, Inc. obtained CE certification under the EU MDR and UKCA certification in the United Kingdom for its latest hardware and eighth-generation AI-powered software. The system the company is introducing to the European markets is commercialized in the U.S. and is the highest performing Swoop® system to date in terms of image quality and usability. Introducing the Swoop® system into international markets is a significant step in supporting the commercial growth of Hyperfine, Inc. The Swoop® system can expand the existing imaging market with its transformative, affordable, and accessible platform to serve more clinicians and patients needing brain imaging.

“There is a growing global demand for accessible MR brain imaging, which the versatile Swoop® system can meet. These strategic distributor partnerships enable a broader market footprint for our business beyond our direct commercial team in the U.S. The clinical applications of our Swoop® system in international markets will also expand from critical care inside hospitals to other professional healthcare facilities such as outpatient clinics and offices. The use of the Swoop® system in Alzheimer’s disease and acute stroke represent significant additional opportunities for our business globally,” said Maria Sainz, President and CEO of Hyperfine, Inc. “We are very encouraged by the high interest level and positive feedback from international clinicians thus far.”

Hyperfine, Inc. also announced the expansion of its management team with Enrico Barini joining as International Business Development Director. In this role, Mr. Barini will build the framework for the company’s business in Europe and drive the international introduction of the Swoop® system by building awareness and adoption. Mr. Barini joins the company with deep expertise in commercial operations and extensive imaging and capital experience, most recently from ViewRay, Inc. and Boston Scientific Corporation.

"We are thrilled to embark on the exciting journey of bringing the Swoop® system to additional global markets," said Dave Castiglioni, VP of Commercial at Hyperfine, Inc. "By expanding into these markets, we can revolutionize healthcare delivery and significantly impact patient outcomes and cost of care. We are committed to leveraging our expertise and partnerships to drive positive change in global healthcare.”

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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