Hyperfine Expands Global Market Reach with New Distribution Partnerships in European and Middle Eastern Markets

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Strategic agreements set the stage for further global adoption of portable MR brain imaging technology, fueling expansion plans for 2025.

GUILFORD, Conn.--(BUSINESS WIRE)--Dec. 17, 2024-- 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—today announced further global expansion of its commercial operations through agreements with experienced distributors to support commercial expansion plans of the Swoop® system into Turkey, Israel, and Saudi Arabia. These distribution agreements strengthen the company's global expansion strategy, broadening access to MR brain imaging in regions with large populations, low penetration of MRI, and significant unmet healthcare needs.

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The Swoop® Portable MR Imaging® System (Photo: Business Wire)

"We have achieved several milestones throughout 2024 that have positioned us for significant growth in international markets in 2025," said David Castiglioni, Hyperfine Chief Commercial Officer. "Agreements with these new partners build on our existing distribution networks, giving Hyperfine robust global reach. The interest from international clinicians and healthcare facilities reflects the growing global enthusiasm for portable MR brain imaging and its potential to bridge critical healthcare gaps."

The new distribution agreements in Turkey, Israel, and Saudi Arabia add to agreements established earlier in 2024 targeting future expansion across thirteen European markets, India, Malaysia, and Indonesia—broadening the reach of Hyperfine to encompass North America, Europe, Asia, Oceania, and the Middle East. In October 2024, Hyperfine was granted CE approval in Europe for its latest ninth-generation AI-powered software. This most recent software approval, combined with the extensive distribution network, positions Hyperfine for significant growth in 2025 and beyond.

The new distribution partnerships ensure efficient market entry and afford Hyperfine strong local support for adopting the Swoop® system. These areas, home to over 100 million people, face challenges in providing timely neurological care, particularly in remote and emergency settings lacking access to advanced imaging equipment. With its portability and cost-effectiveness, the Swoop® system eliminates barriers posed by conventional MRI systems, enabling clinicians to deliver high-quality imaging at the point of care.

"We feel the Swoop® system can play a very valuable role in advancing neurological care globally," added Castiglioni. "International markets have significantly lower penetration of conventional MRI, and a portable and affordable MR brain imaging option is a valuable solution to serve large areas of unmet need in those markets."

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 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 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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