Hyperfine Announces European Launch with CE Approval

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CE approval of the latest generation Swoop® system software is a significant milestone in Hyperfine's international strategy, allowing broader European commercial expansion.

GUILFORD, Conn.--(BUSINESS WIRE)--Nov. 7, 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 CE approval of its latest generation of AI-powered Swoop® system software under the European Medical Device Regulation (MDR, EU No. 2017/745). This approval marks a significant step in positioning Hyperfine for broad European launch of the Swoop® Portable MR Imaging® system, enabling faster, high-quality MR brain imaging that supports critical diagnostic decisions across diverse healthcare settings.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20241107071686/en/

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

Hyperfine secured initial CE certification for the Swoop® system in 2023. Earlier this year, Hyperfine significantly expanded its global distribution network with partnerships established in thirteen European countries, including the five major European markets. This strategic expansion aims to enhance access to advanced portable brain MR imaging technology across diverse healthcare settings worldwide.

"We are thrilled to announce CE approval for the latest generation of AI-powered software for the Swoop® system, marking a pivotal step toward making advanced brain imaging technology accessible across the globe," shared David Castiglioni, Hyperfine Chief Commercial Officer. "With a broad international distribution network in place and the latest software being CE-approved, we are well positioned for commercial expansion. We are committed to transforming healthcare through innovative, cost-effective solutions that address long-standing barriers to MRI access, and we look forward to expanding our collaboration with European healthcare leaders and providers to improve brain MRI access and patient outcomes across the region."

The Swoop® System Software

Scan time reductions in the most recent software may enable Swoop® system images to help speed up the diagnostic process in professional acute care settings, which is crucial for time-sensitive medical conditions such as stroke, where every second counts. Reducing the overall acquisition time for sequences can also decrease the negative impact of patient motion on image quality.

"CE approval of the latest generation of Swoop® system software is an important advance in making rapid MR brain imaging accessible in emergency department settings across Europe," shared Dr. Keith Muir of the University of Glasgow. "Our experience with the ultra-low-field Swoop® system in acute stroke cases has highlighted the benefits of combining diagnostic sensitivity and specificity with portability, enabling faster diagnosis and treatment initiation than routine high-field MRI. Scan speed enhancement with this new software will further improve efficiency and patient tolerability and support critical decision-making in time-sensitive scenarios."

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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