FDA Clears the Inmedix® CloudHRV™ System for Accurate Heart Rate Variability Measurement.

US clinicians now have access to accurate, up-to-date, medical grade heart rate variability (HRV) for clinical care.

NORMANDY PARK, WA, UNITED STATES, January 23, 2025 /EINPresswire.com/ -- Inmedix®, Inc. ("Inmedix") announced today that the US FDA has cleared the Inmedix CloudHRV™ System for US commercialization. This is the first system cleared by the FDA as a cloud-based, heart rate variability (HRV) diagnostic calculated from a high-fidelity 5-min electrocardiogram (ECG) which also includes Bayefsky indices of parasympathetic and sympathetic activity. It represents a milestone in modern HRV assessment with scalability, precision and affordability for patients and clinicians in the clinical setting.

Working with the Inmedix team, the 510(k) submission was created by consultants Starfish Medical in Victoria, BC Canada and overseen by Michael A. Daniel and Mark Smutka of Daniel & Daniel Consulting; with additional expertise provided by rheumatologist and biopharmaceutical consultant Vibeke Strand, MD; Lee S. Simon, MD, rheumatologist and former Division Director at the FDA; and cybersecurity consultant Jonathan Ward at Ward Sciences and Consulting LLC.

"I could not be more grateful to the Inmedix team and our consulting partners for their dedication and attention to detail in this clearance effort," said Inmedix CEO, Co-founder and rheumatologist Andrew J Holman MD. "I am also very appreciative of the careful and thoughtful engagement that the FDA applied in this review process of our complex, cloud-based mathematics."

HRV provides indirect measures of the sympathetic (fight or flight) and parasympathetic (rest/restorative) components of the human autonomic nervous system (ANS). For medical grade HRV, a precision ECG is used to identify each heartbeat and to measure the precise timing between beats. These ECG measurements of heart rate (pulse) variability over time reflect how the autonomic nervous system (ANS) influences cardiac rhythm during respiration. Subsequently, mathematical formulae can be applied to render HRV indices of sympathetic and

parasympathetic activity.

Of note, CloudHRV is not indicated for any specific application in medicine. Its utility is determined exclusively by the clinician and the CloudHRV ECG display is contraindicated for use to monitor or diagnose cardiovascular disease.

ABOUT INMEDIX, INC. AND SUBSIDIARY, INMEDIX, UK LTD.

Seattle-based biotech/medtech Inmedix, Inc. and its subsidiary Inmedix UK, Ltd., are committed to engaging in world class research to discover innovative solutions for pressing healthcare needs related to the impact of stress modulated within the brain by the autonomic nervous system (ANS).

NOTICE:

This Press Release contains certain forward-looking statements, including without limitation statements regarding Inmedix's plans for preclinical studies, effectiveness of its research, product capabilities and the market's demand for its respective products. You are cautioned that such forward-looking statements are not guarantees of future performance and involve risks and uncertainties inherent in Inmedix's business which could significantly affect expected results, including without limitation, progress of development, clinical testing, regulatory approval, developments in raw material, personnel costs, sales as well as legislative, fiscal, and other regulatory measures. Any forward-looking statements are qualified in their entirety by this cautionary statement, and Inmedix undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release. This is not an offer to sell or an offer to purchase securities.

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