DIAGNOS to File for FDA Pre-Market Authorization of Its AI-Powered CARA SYSTEM and Engages Ora as Regulatory Specialist

written by Raj Shah | February 25, 2025

February 25, 2025 (Source) – Diagnos Inc. ("**DIAGNOS**" or the "**Corporation**") (TSX Venture: ADK, OTCQB: DGNOF, FWB: 4D4A), a pioneer in early detection of critical health issues through the use of its FLAIRE platform based on Artificial Intelligence (*AI*), is pleased to announce that it is officially filing for U.S. Food and Drug Administration (FDA) pre-market authorization of its CARA SYSTEM, a machine-learning-enabled medical device (MLMD). To ensure a smooth regulatory process, DIAGNOS has engaged **ORA**, a leading clinical research organization specializing in regulatory affairs and clinical development for ophthalmic products.

The CARA SYSTEM is designed to assist optometrists and frontline healthcare professionals in analyzing fundus images for the early detection of diabetic retinopathy, age-related macular degeneration, and hypertensive retinopathy. By leveraging Artificial Intelligence, DIAGNOS aims to enhance diagnostic accuracy, streamline workflows, and improve patient outcomes on a global scale.

Strategic Partnership to Facilitate U.S. Market Entry

This collaboration with ORA represents a major milestone in DIAGNOS' expansion strategy. With extensive experience in

guiding ophthalmic products through regulatory approvals, ORA will play a pivotal role in navigating the U.S. regulatory landscape and ensuring a successful FDA submission process.

“DIAGNOS is committed to revolutionizing eye health through Artificial Intelligence technologies,” said André Larente, CEO of DIAGNOS. “Our expertise in Artificial Intelligence driven diagnostics is helping to improve patient outcomes worldwide. The optometry market comprises over 300,000 sites globally, and our recent partnership with the largest player in the industry will significantly boost our visibility. Additionally, our government-related business initiatives are resuming, marking an exciting phase of growth for DIAGNOS.”

About ORA
ORA is the world’s leading full-service ophthalmic drug and device clinical research organization. For over 45 years, we have proudly helped our clients earn more than 85 product approvals. We support a wide array of organizations, from start-ups to global pharmaceutical and device companies, to efficiently bring new therapies from concept to market. We bring together the world’s most extensive and experienced team of ophthalmic experts, operations professionals, and management executives to maximize the value of new product initiatives. For more information, please visit www.oraclinical.com and follow us on LinkedIn.

About DIAGNOS
DIAGNOS is a publicly traded Canadian corporation dedicated to early detection of critical health problems based on its FLAIRE Artificial Intelligence (AI) platform. FLAIRE allows for quick modifying and developing of applications such as CARA (Computer Assisted Retina Analysis). CARA’s image enhancement algorithms provide sharper, clearer and easier-to-analyze retinal images. CARA is a cost-effective tool for real-time screening of large

volumes of patients.

Additional information is available at www.diagnos.com and www.sedarplus.com.

This news release contains forward-looking information. There can be no assurance that forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated in these statements. DIAGNOS disclaims any intention or obligation to publicly update or revise any forward-looking information, whether as a result of new information, future events or otherwise. The forward-looking information contained in this news release is expressly qualified by this cautionary statement.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.