MedyMatch Receives Expedited Access Pathway / Breakthrough Device Designation from the FDA to Accelerate Market Access for Intracranial Hemorrhage Software

Tel Aviv, Israel – January 29, 2018 – MedyMatch Technology, a company focused on helping physicians provide accurate patient assessment through artificial intelligence (AI)-based insights, today announced that it has been granted Expedited Access Pathway (EAP) designation by the United States Food and Drug Administration (FDA) for intracranial hemorrhage detection.

This software medical device, based on deep learning technologies, automatically analyzes non-contrast head CT images. It is designed to be highly sensitive to the presence of intracranial hemorrhage (ICH) in these scans and to alert the treating physician when ICH is detected. Non-contrast head CT is the standard for initial assessment of potential ICH in emergency medicine settings.

The EAP program is designed to facilitate rapid patient access to medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. Under the 21st Century Cures Act, EAP devices will be transitioned to FDA's Breakthrough Device program.

"We are delighted to be working closely with FDA on bringing this ICH breakthrough, a first-in-class hemorrhage detection tool, to clinicians," said Gene Saragnese, Chairman & CEO of MedyMatch. "As the population grows older and lives longer and as more treatment options become available, MedyMatch is positioned to assist clinicians in making assessments that can ultimately save lives and minimize disability while utilizing healthcare resources in the best way possible."

"FDA's Expedited Access Pathway and Breakthrough Device designation gives us the opportunity to accelerate the development and approval process of our intracranial hemorrhage software in the United States," said Dr. Joshua Schulman, Vice President of Clinical, Regulatory and Quality Affairs. "This designation is a recognition of both the need for new assessment tools for intracranial hemorrhage and an affirmation of MedyMatch's technical approach to assisting clinicians who need to make time-sensitive yet accurate decisions in emergency settings. We look forward to working with FDA to bring the ICH application to market quickly."

MedyMatch has developed a broad machine vision and deep learning platform to support the assessment of multiple clinical indications. MedyMatch's team of AI, deep learning and machine vision experts is working with world-class clinical and industry partners to yield unprecedented insights into medical data. The first of these applications will be the detection of intracranial hemorrhage. Accurate and timely detection of ICH is a critical step in clinical decision making for stroke assessment and head trauma. Working with its development and distribution partners, MedyMatch is on a mission to make all caregivers confident, life-saving experts every time and in all locations through AI-enabled clinical decision support at the point of care.

About MedyMatch

Based in Tel Aviv, Israel, MedyMatch is a leading medical A.I. company delivering a clinical decision support platform to improve patient outcomes in acute medical scenarios. The platform can be natively integrated into PACS systems, medical imaging hardware or healthcare clouds. To learn more, please visit https://www.medymatch.com. Join the conversation at #medymatch and follow us on twitter at @medymatch.

Press Contacts:
Michael Rosenberg
MedyMatch Technology Ltd.
press@medymatch.com