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Amprion's PMCA technology receives Breakthrough Device Designation from U.S. FDA

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The company anticipates market roll-out of FDA-approved early detection testing for Parkinson's within 18 months.

Amprion has announced that its proprietary technology, Protein Misfolding Cyclic Amplification (PMCA) using CSF and plasma alpha-Synuclein (?S) to aid in the diagnosis of Parkinson's disease, received a Breakthrough Device designation from U.S. FDA.

"Prions are proteins gone rogue. This is a small victory in our war against Prions," says Amprion CEO Russ Lebovitz, M.D./PhD. "We are honored and look forward to working closely with FDA to fast-track the development and review of our aS PMCA tests toward final regulatory approval. Early diagnosis of Parkinson's represents a giant leap for science to crack the code on this disease. Our goal is to stop Parkinson's on its destructive path."

FDA's Breakthrough Devices Program is designed to speed up development, assessment and review of medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Parkinson's disease currently affects approximately 10 million people worldwide. Despite tremendous capital expenditures in research and drug development, there are still no effective treatments. Why?

"There is no specific, sensitive and objective laboratory test for the diagnosis of Parkinson's disease presently. Patients are now diagnosed based on clinical symptoms, which means the disease is relatively advanced," explainsClaudio Soto, PhD, Amprion's co-founder and chief scientific officer who also serves as professor of neurology at McGovern Medical School at UTHealth. "Our PMCA test tracks alpha-Synuclein, a protein that misfolds into toxic shapes in the brain and this likely begins decades before disease symptoms. Amprion's ability to monitor Misfolded Proteins at early stages is both significant and meaningful. This enables us to work with major pharmaceutical companies to develop Prion-targeted drugs to stop or slow the disease."

Dr. Lebovitz acknowledges the support of three key partners in the development of Amprion's breakthrough technology: The Michael J. Fox Foundation for Parkinson's Research, National Institutes of Health SBIR/STTR programs and McGovern Medical School at the University of Texas Health Science Center at Houston.

"Efforts across Parkinson's research seek to better define, measure and treat alpha-Synuclein pathology. This assay is a valuable tool in that work and we're proud that The Michael J. Fox Foundation could partner toward its development with funding, samples and consult," said Samantha Hutten, PhD, senior associate director of research partnerships at The Michael J. Fox Foundation for Parkinson's Research.

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Amprion pioneers Prion Early Detection Testing for Alzheimer's and Parkinson's. Its breakthrough technology tracks specific Prion biomarkers including Abeta, Tau and Synuclein, prior to any clinical symptoms using CSF and blood. Early detection accelerates drug development pathways to stop the disease. The company anticipates launching early detection diagnostics in the next 18 months.