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MRI Interventions Congratulates Voyager Therapeutics on First Patient Dosing in RESTORE-1, the Phase 2 VY-AADC Gene Therapy Trial for Parkinson's Disease

IRVINE, Calif. , Dec. 10, 2018 (GLOBE NEWSWIRE) -- MRI Interventions, Inc. (OTCQB:MRIC), a platform neurosurgery company with products designed for navigation, ablation and gene therapy, today announced participation in the RESTORE-1 gene therapy trial for Parkinson's disease sponsored by Voyager Therapeutics. Under the agreement with Voyager, MRI Interventions provided the navigation system and drug infusion cannulae, as well as clinical support during the procedure to assist the Voyager team in executing the clinical protocol.

"Patients with Parkinson's disease need new therapeutic options, especially as the disease progresses and there is less AADC enzyme in parts of the brain where it is needed to convert levodopa to dopamine," said Mark Richardson, M.D., Ph.D., Associate Professor, Director of Epilepsy and Movement Disorders Surgery at the University of Pittsburgh Medical Center and principal investigator in the RESTORE-1 trial. "Voyager's VY-AADC is an experimental gene therapy that is designed to deliver the AADC gene into brain cells where the enzyme can be produced to increase dopamine production. We are excited to contribute to this Phase 2, placebo-controlled trial of VY-AADC in patients with Parkinson's disease."

"We are thrilled that the next stage in the regulatory pathway for Voyager's Parkinson's disease program is now underway, and that our team is working side-by-side with the Voyager team to provide both products and clinical services," commented Joe Burnett, President and CEO of MRI Interventions. "Our relationship with Voyager is a highlight of our Biologics and Drug Delivery growth pillar, under which we offer product, clinical services and research and development work for our gene therapy partners. Our goal is to act as an extension of biologics companies into the navigation and medical device space. This allows our partners to focus fully on what they do best in the therapeutic side of the equation and to trust us to get the therapy to the right place with efficiency and precision. We are making strides to replicate our relationship with Voyager with other gene and drug companies to treat some of the most challenging neurological disorders."

About the RESTORE-1 Phase 2 trial of VY-AADC for Parkinson's Disease
The Phase 2 RESTORE-1 trial seeks to enroll patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral

medications, and have at least three hours of OFF time during the day as measured by a validated self-reported patient diary. Patients who meet the eligibility criteria will be randomized (1:1) to one-time administration of VY-AADC (for a total dose of up to 2.5×10^{12} vector genomes) or placebo surgery.

The primary endpoint of RESTORE-1 is ON time without troublesome dyskinesia, or good ON time, as measured by a self-reported patient diary at 12 months. Secondary endpoints include diary OFF time, other motor function and quality of life measures from the United Parkinson's Disease Rating Scales (UPDRS-II,-III scores), the Parkinson's Disease Questionnaire (PDQ-39), and patient's global function as measured by the proportion of participants with improvement on the Clinical Global Impression (CGI) score. The trial will also measure non-motor symptoms from the Non-Motor Symptom Scale (NMSS), as well as safety.

Biomarker data include measurements of the coverage of the specific region of the brain (putamen) targeted with VY-AADC and measurements of AADC enzyme expression and activity in the putamen measured by positron emission tomography (PET) using fluorodopa F-18. Changes in patients' daily doses of oral levodopa and related medications will also be recorded.

For additional information regarding Voyager's RESTORE-1 Phase 2 clinical trial with its gene therapy VY-AADC for the treatment of Parkinson's disease, please use the following link or email Voyager at clinicaltrials@vygr.com.

About MRI Interventions, Inc.
Building on the power of magnetic resonance imaging ("MRI"), MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain. The ClearPoint Neuro Navigation System, which has received 510(k) clearance and is CE marked, utilizes a hospital's existing diagnostic or intraoperative MRI suite to enable a range of minimally invasive procedures in the brain. For more information, please visit www.mriinterventions.com.

Forward-Looking Statements
Statements herein concerning MRI Interventions, Inc.'s plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the company's future events, developments and future performance, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the Company's ability to obtain additional financing; estimates regarding the sufficiency of the Company's cash resources; future revenues from sales of the company's ClearPoint Neuro Navigation System products; and the company's ability to market, commercialize and achieve broader market acceptance for the company's ClearPoint Neuro Navigation System products. More detailed information on these and additional factors that could affect the company's actual results are described in the "Risk Factors" section of the company's Annual Report on Form 10-K for the year ended December 31, 2017, and its Quarterly Report on Form 10-Q for the three months ended September 30, 2018, both of which have been filed with the Securities and Exchange Commission.

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