

# MRI Interventions' ClearPoint System Enables Precise Delivery of Promising Investigational Gene Therapy in Parkinson's Disease Phase I Clinical Trial

First Patient Treated in Phase I Safety Study Led by Researchers at University of California, San Francisco (UCSF) and National Institutes of Health (NIH) and Utilizing uniQure's GDNF Gene

IRVINE, CA -- (Marketwired) -- 08/12/13 -- MRI Interventions, Inc. (OTCQB: MRIC) today announced treatment of the first patient in a Phase I clinical trial utilizing uniQure B.V.'s glial cell line-derived neurotrophic factor (GDNF) for treatment of Parkinson's disease. This gene therapy holds promise in the battle against the degenerative and debilitating disorder, which affects 1.5 million people in the United States. MRI Interventions' <u>ClearPoint Neuro</u> <u>Intervention System</u> is being used in the clinical trial to enable direct infusion of the gene therapy into an area of the brain affected by Parkinson's disease.

Dr. Krystof Bankiewicz, MD, PhD at University of California, San Francisco (UCSF), and Dr. John D. Heiss, MD at the National Institute for Neurological Disorders and Stroke, part of the National Institutes of Health (NIH), are leading the trial. uniQure B.V., a leader in human gene therapy, is providing the GDNF gene. uniQure made headlines last November by receiving regulatory approval in Europe of a first-in-class gene therapy to treat orphan diseases.

The hypothesis of the Parkinson's disease trial is that GDNF's neuro-regenerative and protective properties may protect and strengthen brain cells that produce dopamine, a chemical that affects brain function. In Parkinson's disease, dopamine production is reduced in an area of the brain responsible for movement, which leads to the debilitating symptoms experienced by many patients with the disease. The affected area is a tiny spot located deep within the brain, and the ClearPoint System provides the visualization and precision necessary to deliver a desired amount of the gene therapy directly to this very small target without disrupting other critical neurological structures in the process.

"The success of gene therapy in patients requires accuracy in delivery," said Dr. Krys Bankiewicz of UCSF. "The ClearPoint System enables this precision, with the safe and accurate infusion of our gene therapy product into a miniscule target in the brain while we

observe the procedure and confirm results in real time."

"We are very pleased with our first patient procedure," Dr. Heiss stated. "The ClearPoint System worked exceptionally well, enabling us to achieve precision targeting into the putamen and to observe administration of the therapeutic agent as it occurred."

The ClearPoint navigation platform is the only technology to enable minimally-invasive neurosurgery under continuous MRI guidance, offering surgeons a direct view of the inside of a patient's brain during a procedure.

"We are delighted to be working with UC San Francisco, the National Institutes of Health and uniQure, to help advance a novel treatment for Parkinson's disease," said Kimble Jenkins, CEO of MRI Interventions.

"At uniQure we are convinced that success for gene therapy requires the most advanced and reliable delivery technologies," said uniQure CEO Jörn Aldag. "Together with our collaborators at UCSF, the NIH and MRI Interventions, we are paving the way to further advances in the treatment of Parkinson's Disease."

The study, sponsored by the NIH, is a Phase I open-label dose escalation safety study that will include 24 patients over 4 cohorts. The first patient was dosed on May 20 and there have been no safety issues.

## About MRI Interventions, Inc.

Founded in 1998, MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain and heart. Utilizing a hospital's existing MRI suite, the company's FDA-cleared and CE-marked ClearPoint<sup>®</sup> system is designed to enable a range of minimally invasive procedures in the brain. MRI Interventions has a co-development and co-distribution agreement with Brainlab, a leader in software-driven medical technology, relating to the ClearPoint system. In partnership with Siemens Healthcare, MRI Interventions is developing the ClearTrace<sup>®</sup> system to enable MRI-guided catheter ablations to treat cardiac arrhythmias, including atrial fibrillation. Building on the imaging power of MRI, the company's interventional platforms strive to improve patient care while reducing procedure costs and times. MRI Interventions is also working with Boston Scientific Corporation to incorporate its MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications. For more information, please visit www.mriinterventions.com.

# About uniQure

uniQure is delivering on the promise of gene therapy, single treatments with potentially curative results. We have developed a modular platform to rapidly bring new disease modifying therapies to patients with severe disorders. Our approach is validated by multiple partnerships and the regulatory approval of our lead product Glybera. <a href="https://www.uniqure.com">www.uniqure.com</a>.

### Forward-Looking Statements

Certain matters in this press release may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements often can be identified by words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential,"

"predicts," "projects," "should," "will," "would," or the negative of these words or other words of similar meaning. Forward-looking statements by their nature address matters that, to different degrees, are uncertain and involve risk. Uncertainties and risks may cause MRI Interventions' actual results and the timing of events to differ materially from those expressed in or implied by MRI Interventions' forward-looking statements. Particular uncertainties and risks include, among others: demand and market acceptance of our products; our ability to successfully expand our sales and marketing capabilities; our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including our current product candidates; availability of third party reimbursement; the sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs; future actions of the FDA or any other regulatory body that could impact product development, manufacturing or sale; our ability to protect and enforce our intellectual property rights; our dependence on collaboration partners; the impact of competitive products and pricing; and the impact of the commercial and credit environment on us and our customers and suppliers. More detailed information on these and additional factors that could affect MRI Interventions' actual results are described in MRI Interventions' filings with the Securities and Exchange Commission, including, without limitation, MRI Interventions' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2013. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements contained in this press release to reflect any change in MRI Interventions' expectations or any change in events, conditions or circumstances on which any such statements are based.

#### MRI Interventions contact Information:

MRI Interventions, Inc. David Carlson CFO 901-522-9300

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