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MRI Interventions' ClearPoint(R) System Helps Advance Brain Cancer Clinical Trial of Investigational Gene Therapy Drug Toca 511, Demonstrates Benefits of MRI-Guided Drug Delivery

IRVINE, Calif., April 25, 2013 (GLOBE NEWSWIRE) -- MRI Interventions, Inc. (OTCQB:MRIC) today announced that its ClearPoint® Neuro Intervention System is advancing the minimally-invasive precision delivery of the investigational gene therapy drug Toca 511 into malignant brain tumors. The procedure is being performed under real-time visualization and direct magnetic resonance imaging (MRI) guidance at select clinical trial sites. Highlights of the ClearPoint System's application in the Toca 511 trial include:

Improved flow rates during drug delivery. The recently-introduced SmartFlow® large-bore cannula increases the drug delivery rate threefold over documented flow rates of the original SmartFlow cannula. Like the original SmartFlow cannula, the new cannula incorporates a stepped tip design to prevent reflux and leakage of the drug outside of the target area, but the new cannula's large bore allows for a clinically meaningful increased rate of delivery.

Precise delivery of the therapeutic agent into the brain tumor. Direct visualization of the procedure in real-time allows surgeons to monitor and confirm delivery to the tumor of Toca 511 mixed with MRI contrast agent at the time of infusion.

Multiple trajectories in a single case. The ClearPoint System includes a SmartFrame® targeting device that works with software to allow convenient repositioning of the cannula for multiple trajectories in a single case, and an adjustable head stabilization device that accommodates a wide range of possible entry points.

[Tocagen Inc.](#), the clinical trial sponsor, is developing the investigational drug Toca 511 (vocimagene amiretrorepvec) in combination with Toca FC (an investigational extended-release formulation of 5-FC) for the treatment of recurrent high grade glioma, including glioblastoma multiforme (GBM, Grade IV glioma), the most common and aggressive form of brain cancer. Toca 511 is a retroviral replicating vector (RRV) encoding the genetic instructions for the enzyme cytosine deaminase (CD). Toca 511 is designed to selectively infect dividing cancer cells and spread through the tumor after administration. Each patient then begins a course of Toca FC. Within infected cells the CD enzyme converts 5-FC to the anti-cancer drug 5-FU. By producing 5-FU locally, this technology has the potential to produce much higher concentrations of 5-FU in the tumor than can be safely attained with systemic administration.

"So far we successfully delivered Toca 511 precisely to the brain cancer in three patients, all of whom went home the next day," said Manish Aghi, MD, a neurosurgeon and principal investigator for the Toca 511 trial at University of California, San Francisco. "This new ability to deliver large volumes of Toca 511 rapidly into the tumor at flow rates up to 1.8 ml/h (30 microliters a minute) under real-time visualization represents a major technological advance that will enable the neurosurgeon to accurately deliver large quantities of a therapeutic agent, while providing the patient the benefit and safety of a minimally-invasive procedure."

"Our collaboration with Tocagen underscores the advantages of real-time MRI-guided delivery of therapeutic agents to the brain, and we are pleased to be a key contributor to the rapid progress being achieved," said Kimble Jenkins, CEO of MRI Interventions.

Each year approximately 10,000 new cases of GBM are diagnosed in the US. In a recent population-based study, median survival in all diagnosed patients was 10 months.

Tocagen is presently enrolling patients in its investigational Phase I clinical trials. Currently, University of California,

San Francisco, University of California, San Diego, Cleveland Clinic Foundation, and Henry Ford Hospital in Detroit are enrolling patients, and additional sites are in the process of joining this study. For more information about participating in this study, please submit an [inquiry form](#) to Tocagen.

Upcoming Conferences

Dr. Aghi will be presenting data from the Tocagen trial on May 5 at the [Targeted Drug Delivery Conference](#) in San Francisco, and the ClearPoint system will be exhibited at the [Annual Scientific Meeting](#) of the American Association of Neurological Surgeons (AANS) in New Orleans, April 27-May 1.

About the ClearPoint® Neuro Intervention System

Traditionally, delivery of drug therapies to brain tumors has been performed with neuro-navigation, a computer-assisted technology utilized by neurosurgeons that does not provide for direct visualization of drug delivery in real-time. The ClearPoint System, which is in commercial use in the U.S. for a variety of minimally-invasive neurosurgical procedures, is designed to allow real-time, direct visualization during neurosurgery. MRI Interventions and its distributor Brainlab have partnered to enable neurosurgeons to visualize local drug delivery to the brain and central nervous system using the ClearPoint platform, and the system is currently being used to enable delivery of investigational therapeutics in five clinical trials. In addition to drug delivery, asleep deep brain stimulation, focal laser ablation, and biopsy are also common uses of the ClearPoint platform. The ClearPoint SmartFlow® cannula is presently FDA-cleared for injection of cytarabine, a chemotherapy drug, to the ventricles or removal of CSF from the ventricles during intracranial procedures. Delivery of Toca 511 using the SmartFlow cannula is investigational.

About Tocagen Inc.

Tocagen Inc. is a privately funded, clinical stage biopharmaceutical company pursuing the discovery, development and commercialization of gene therapy products for the treatment of cancer. Tocagen is initially focusing on treatments for patients with advanced cancer for whom no adequate treatments currently exist. Toca 511 & Toca FC, the company's lead investigational combination product candidate, is being evaluated in clinical trials in patients with recurrent high grade glioma (such as glioblastoma multiforme). Tocagen has received grant support from leading brain cancer foundations including, Accelerate Brain Cancer Cure ([ABC2](#)), the National Brain Tumor Society ([NBTS](#)), the American Brain Tumor Association ([ABTA](#)), and the Musella Foundation. For more information about Tocagen or Toca 511 please visit: www.tocagen.com.

About MRI Interventions

Founded in 1998, MRI Interventions (OTCQB:MRIC) is a publicly traded company 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 ClearPoint® 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® 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.

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. For MRI Interventions, particular uncertainties and risks include, among others: demand and market acceptance of its products; its ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including its current product candidates; availability of third party reimbursement; the sufficiency of its 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; its

ability to protect and enforce its intellectual property rights; its dependence on collaboration partners; the retention of its sales representatives and independent distributor; the impact of competitive products and pricing; and the impact of the commercial and credit environment on it and its 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' most recent annual report on Form 10-K. 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.

CONTACT: David Carlson
Chief Financial Officer
MRI Interventions, Inc.
901-522-9300

Source: MRI Interventions, Inc.