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# Importance of Real-Time MRI Guidance in Delivery of Toca 511 Gene Therapy Directly to High Grade Glioma Presented at Annual Society for Neuro-Oncology Scientific Meeting

## Clinical Data From Ongoing Study Shows Real-Time MRI Guidance, Enabled by MRI Interventions' ClearPoint System, Provides Greater Reliability in Drug Delivery to Brain Tumors and Allows Infusion at Multiple Tumor Locations in a Single Procedure

IRVINE, Calif., Dec. 3, 2013 (GLOBE NEWSWIRE) -- MRI Interventions, Inc. (OTCQB:MRIC) today announced the presentation of clinical data demonstrating the precision of MRI-guided delivery of the investigational gene therapy Toca 511 to high grade gliomas using the company's ClearPoint® Neuro Intervention System as the delivery platform. At the 4th Quadrennial Meeting of the World Federation of Neuro-Oncology, held in conjunction with the 18th Annual Society for Neuro-Oncology Scientific Meeting and Education Day, Dr. Manish Aghi, neurosurgeon at University of California, San Francisco (UCSF), presented a poster showing interim data from an ongoing Phase I clinical trial evaluating the safety and tolerability of Toca 511 in combination with Toca FC in recurrent high grade glioma patients.

Toca 511 is a retroviral replicating vector that carries a gene for an enzyme that converts orally delivered Toca FC (extended-release 5-FC) into 5-FU, a potent anti-cancer agent.

The Toca 511 delivery procedure uses MRI Interventions' ClearPoint System, which merges neuronavigation with real-time MRI imaging. This platform allows visualization while making adjustments to cannula trajectory, position and flow rate during a delivery procedure.

Dr. Aghi commented that real-time MRI-guided delivery is more precise than delivery based on previous methods. "Direct visualization of the tumor during delivery of Toca 511 has been very important in helping us administer the desired dose precisely at the intended location," stated Dr. Aghi. "The evidence of antitumor activity we have observed in this trial support continued dose escalation."

Additional highlights of the presentation included:

- Toca 511 dose levels studied to date have been safe and well-tolerated;
- Using direct MRI guidance, delivery of Toca 511 into as many as four locations in the tumor, at flow rates of up to 30 µL/min has been achieved without reflux;
- Analysis of tumor from a patient who underwent MRI-guided delivery of Toca 511 showed Toca 511 gene expression;
- In certain patients, following treatment with Toca 511 and Toca FC, MRI changes consistent with antitumor activity have been observed.

"We are pleased to be a part of the ongoing progress in the development of new treatment options for patients with high grade gliomas," stated Kim Jenkins, CEO of MRI Interventions, Inc. "We are optimistic that direct visualization for precise delivery of investigational gene therapies like Toca 511 will have a positive impact on the field of neuro-oncology."

Tocagen is presently enrolling patients in its investigational Phase I clinical trials. For more information about participating in these studies, please submit an inquiry form to Tocagen.

**About the ClearPoint System**

The ClearPoint® System is a navigation platform designed to allow real-time, direct visualization during minimally-invasive neurosurgical procedures. ClearPoint software works with MRI to assist surgeons in planning a target and trajectory, and the SmartFrame® targeting device enables the MRI-guided alignment and insertion of surgical instruments.

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 other therapeutic agents using the SmartFlow cannula is investigational.

**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 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 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 clinical support capabilities; 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 November 13, 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.

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