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MEDIA CONTACT:
Blake Marler
Director, Corporate Communications
(704) 936-1824 / blakemarler@ushifu.com

US HIFU TO FUND LANDMARK INVESTIGATION OF FOCAL THERAPY FOR PROSTATE CANCER

University of College London Hospital Study
Marks Premier Multi-Center Focal Therapy for Prostate Cancer Trial

CHARLOTTE, N.C., FEBRUARY 24, 2010—US HIFU, a world leader in minimally invasive high intensity focused ultrasound (HIFU) technologies and manufacturer of the Sonablate® 500 medical device, has announced its intention to fund a landmark multi-center trial to study focal therapy for localized prostate cancer. Mark Emberton, M.D., (FRCS-Urology), Consultant Urological Surgeon and Divisional Clinical Director of Cancer Services at University College London Hospital (UCLH), along with Hashim Uddin Ahmed, MRC Clinical Research Fellow, will lead the trial.

The primary objectives of the trial are to evaluate quality of life outcomes and safety of focal therapy in the treatment of localized prostate cancer. A secondary objective is to measure the costs of treatment and model the cost-effectiveness of focal therapy using US HIFU's proprietary Sonablate 500 technology. The study will involve four centers initially and may expand to as many as 10 centers in the U.K.

"I believe that focal treatment is the future for early-stage, low-risk cancer. Considering the treatments that are currently approved and available worldwide, men with localized prostate cancer may often feel they must choose between active surveillance and radical therapy (surgery or radiation)," said Dr. Emberton. "Patients who opt to monitor their cancer run the risk of having the disease spread, while those who choose radical therapy are at increased risk for incontinence and impotence. I see focal therapy as a cost-effective solution that can potentially provide an optimal balance between cancer control and co-morbidity issues."

Naren Sanghvi, US HIFU's Chief Scientific Officer, said, "The management of prostate cancer is entering a time of dramatic change. While surgery and radiation therapy will continue to play important roles in the treatment of some patients, new approaches designed to serve those with minimal, focal or slow-growing cancer, for example, deserve scholarly attention and merit evaluation in bona fide clinical trials. The Emberton Study, supported by US HIFU, attempts to address issues central to an emerging new paradigm in cancer management which could be termed 'therapeutic surveillance.' The goal of therapeutic surveillance would be focal, possibly repetitive, cancer ablation with minimal morbidity facilitated by serial non-invasive imaging."

The ability to accurately and precisely detect cancerous lesions as well as ongoing disease monitoring, and management if necessary, are keys to effective focal therapy and paramount to trial designers. “Over the past year, US HIFU has been working with thought leaders around the world to come up with what we believe is the most well thought-out and defensible trial design to initially evaluate HIFU-induced focal therapy while compensating as thoroughly as possible for the flaws associated with biopsy diagnosis,” said Steve Puckett, Jr., US HIFU’s Chief Executive Officer. “We look forward to discussing the specifics of our trial design with top academic investigators from around the world at the upcoming focal conference in Washington.”

Sonablate HIFU for prostate cancer is a minimally invasive, targeted approach to treating disease with precision-focused ultrasound energy that, when delivered, raises the temperature of the tissue in a matter of seconds. The extreme, rapid-firing heat destroys the tissue at a specific target, known as a lesion, which measures 12x3x3 mm, approximately the size of a grain of rice. Lesions are created throughout the prostate that result in its destruction.

The third annual International Symposium on Focal Therapy and Imaging of Prostate and Kidney Cancer will be held in Washington, D.C. from February 24-27. Dr. Emberton will give three presentations on Friday, Feb. 26 entitled, “Focal HIFU,” “Vascular Targeted Therapy: A Novel Approach to Focal Therapy” and “Patient Selection: Conservative Approach Versus Liberal Treatment.” In addition, Sanghvi will present two abstracts on the tissue change monitoring (TCM) technology now available in the Sonablate 500 and immunotherapy on Wednesday, Feb. 24.

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About US HIFU, LLC

US HIFU, LLC, a privately held healthcare company, is a world leader in minimally invasive high intensity focused ultrasound (HIFU) technologies. US HIFU manufactures the Sonablate[®] 500 medical device and is focused currently on treating primary and recurrent prostate cancer using Sonablate[®] HIFU. The company is engaged in ongoing research for technological advancements for the Sonablate[®] system or other ultrasound applications. US HIFU was founded in 2004 and is headquartered in Charlotte, N.C. Additional information can be found at www.ushifu.com.

About the Sonablate[®] 500

The Sonablate[®] 500 is a minimally invasive medical device that utilizes ultrasound energy to destroy tissue within the body. It was developed by Focus Surgery, Inc. and is manufactured in part by Misonix, Inc. (NASDAQ: MSON), which also holds distribution rights in Europe. Takai Hospital Supply Ltd. distributes the Sonablate[®] 500 in Southeast Asia. The Sonablate[®] 500 is not approved for use in the U.S. The Sonablate[®] 500 remains investigational in the U.S. and is being studied for the treatment of prostate cancer in clinical trials in the U.S. FDA has made no decision as to the safety or efficacy of the Sonablate[®] 500 for the treatment of prostate cancer.