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Walter Reed Army Medical Center offers HIFU for Qualifying Men with Locally Recurrent Prostate Cancer in a Phase III Clinical Trial

CHARLOTTE, NC. MARCH 16, 2009 – Walter Reed Army Medical Center is the latest institution to be added to a number of academic centers involved in a clinical trial that is investigating the safety and efficacy of High Intensity Focused Ultrasound (HIFU) using the Sonablate® 500 for the treatment of locally recurrent prostate cancer following failed external beam radiation therapy (EBRT).

The technology of using HIFU with the Sonablate is a minimally invasive, outpatient procedure that uses a transrectal probe to focus ultrasound energy resulting in a therapeutic rise in heat within the prostate. This results in the focal destruction of prostatic tissue. High Intensity Focused Ultrasound does not use radiation and is non surgical. In a small U.S. safety trial, 91 percent of the participants treated in the study had a negative biopsy at six months.

Some men with prostate cancer who are treated with radiation therapy have a return of their cancer as determined by a rise in their Prostate Specific Antigen (PSA). Many of these men have few alternatives other than hormone therapy. According to the American Cancer Society, possible side effects of hormone therapy include osteoporosis, anemia, loss of muscle mass, depression, and decreased mental acuity.

The principal investigators at Walter Reed Army Medical Center in this study are: MAJ(P) Steven R. Brassell, M.D., and COL David G. McLeod (Ret), M.D., JD.

At this time, eligible participants for the trial must be between the ages of 40 and 80, and have biopsy confirmed local recurrence two or more years following external beam radiation failure. Other selection criteria are applicable for trial entry as well. Patients treated at Walter Reed Army Medical Center must be military beneficiaries.

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“We are pleased to announce the addition of Walter Reed as one of our clinical trial sites. Dr. McLeod has been following the progress of HIFU for many years, and we are fortunate to be able to work with him on this important study. We are honored to be able to offer HIFU to the military patient population at Walter Reed and believe that enrollment will occur swiftly at this site,” said Steve Puckett, Jr., Chief Executive Officer, USHIFU, the company managing the clinical trials with sponsor Focus Surgery, Inc.

This investigational treatment is usually performed on an outpatient basis. Potential risks of the treatment include frequency, urgency, mild discomfort while urinating. Less common side effects may include urinary stricture, retention, incontinence, impotence and rectal fistula.

For more information about enrolling in HIFU trials, please call: 1-877-874-4389 or visit www.ProstateCancerRecurrentTrial.org.

About USHIFU, LLC

USHIFU, based in Charlotte, NC, is a worldwide leader in the development, distribution and use of minimally invasive high intensity focused ultrasound technologies

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 FSI and is manufactured by Misonix, Inc. (NASDAQ: MSON) who also holds distribution rights in Europe. Takai Hospital Supply Ltd. and THS International distribute the Sonablate[®] 500 in Southeast Asia and the Middle East.

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.

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