

InSightec Resumes Clinical Trials for Non-Invasive Treatment of Brain Tumors

Haifa, ISRAEL (September 25, 2007). InSightec Ltd. has begun the second stage of its FDA approved Phase I clinical trial for non-invasive treatment of brain tumors using MR guided Focused Ultrasound Surgery on the ExAblate® system.

The objectives of the study are to evaluate the safety of focused ultrasound delivered through an intact skull and to estimate the effect of the thermal ablation on the tumors. Patients with recurrent and inoperable glioblastomas or cerebral metastases are being recruited for this study.

ExAblate uses high-intensity focused ultrasound waves to ablate (destroy) tissue in combination with Magnetic Resonance Imaging (MRI). The system provides visualization of the tumor and acoustic energy beam path as well as real time thermal feedback that allows the physician to monitor and control the treatment process.

Three patients with recurrent glioblastoma have already been treated at Brigham and Women's Hospital in Boston, evaluating the ability of the ExAblate system to safely reach a targeted tumor. Based on the safety profile submitted for review, the FDA recently approved the continuation of the trial.

“The ExAblate MRgFUS technology has significant potential as a non-invasive and non-ionizing tumor therapy, and offers an important potential alternative or adjunct to radiation therapy, and eventually, for brain surgery” says Ferenc Jolesz, MD Professor of Radiology, Brigham and Women's Hospital, Boston MA.

Dr. Peter Black, Professor of Neurosurgery at the Brigham and Women's Hospital and co-director of the study adds that “The challenge of brain tumor surgery is to achieve complete tumor removal or the greatest possible extent of tumor reduction without causing brain injury. This feasibility study will significantly advance our understanding of the potential of this technology for brain tumor treatment and if successful, prepare the way for a clinical efficacy study.”