

# CLINICAL TRIAL FACT SHEET

## ExAblate (MRI-guided Focused Ultrasound Surgery)

### Treatment of Metastatic Bone Tumors for the Palliation of Pain

A Pivotal Study to Evaluate the Effectiveness and Safety of ExAblate Treatment of Metastatic Bone and Multiple Myeloma Tumors for the Palliation of Pain in Patients Who Are Not Candidates for Radiation

**Trial Description:** This is a randomized, single-blind (patient), placebo-controlled, parallel-assignment, safety/efficacy study for myeloma patients with bone pain who are not candidates, fail, refuse, or their physician does not recommend radiation.

**Trial Objectives:** To assess the effectiveness and safety of ExAblate, which is designed to heat the bone periosteum with focused ultrasound in order to ablate the sensory origin of the patient's pain.

### Major Inclusion Criteria:

- Patients who have painful multiple myeloma bone lesions and are not candidates for radiation.
- Patients who refuse additional radiation therapy
- Patients for whom the treating physician would not prescribe radiation or additional radiation treatments
- Patients with NRS pain score  $\geq 4$  irrespective of medications

### Major Exclusion Criteria:

- Patients who need surgical stabilization of the affected bony structure
- Targeted tumor is at an impending fracture site
- Patients with surgical stabilization of tumor site with metallic hardware
- More than 5 painful lesions.
- Targeted tumor is in the skull
- Patients with standard contraindications for MRI

### Location and Contact Information:

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*(locations continue on next page)*



### International Myeloma Foundation

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## **ExAblate (MRI-guided Focused Ultrasound Surgery)**

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### **Additional Resource**

[www.mycancerpain.org](http://www.mycancerpain.org)

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