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**NEOTHERMIA CORPORATION'S EN-BLOC® BREAST BIOPSY SYSTEM RECEIVES
EXPANDED INDICATIONS FOR TISSUE EXCISION**

NATICK, MA, SEPTEMBER 7, 2005 -- Neothermia Corporation, an emerging leader in the development and marketing of minimally invasive systems for the diagnosis of breast cancer, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for expanded indications of its *en-bloc*® breast Biopsy System for complete or partial removal of an imaged abnormality for histological review.

The *en-bloc*®, which received FDA clearance in 2001, is a vacuum-assisted, image-guided system. *en-bloc*'s slender probe is inserted through a small incision on the breast to remove suspicious tissue for histopathologic analysis. Unlike excisional surgical biopsy, *en-bloc*® is minimally invasive and is conducted in an outpatient setting. To date, more than 15,000 *en-bloc*® procedures have been performed, nationwide.

In addition to the current indication for diagnostic sampling of breast abnormalities, the expanded FDA clearance for the *en-bloc*® Biopsy System is now indicated to provide tissue samples:

- ❖ for histologic examination with partial or complete removal of an imaged abnormality, and;
- ❖ for histologic examination with partial removal of a palpable abnormality that has been classified as benign (e.g., fibroadenoma, fibrocystic lesion).

The expanded indications are based on the results of an evaluation performed at the Oklahoma Breast Care Center. In an evaluation conducted in July of this year, Neothermia's *en-bloc*® breast Biopsy system showed equivalence to Mammotome® core biopsy when totally or partially removing imaged lesions of the breast. During the trial, 15 breast biopsy captures were done under ultrasound guidance using both devices, and another 15 captures were done with each device under stereotactic guidance. Results showed that the *en-bloc*® made complete captures of every imaged target with fewer attempts than required by the Mammotome®.

Commenting on today's news, Christopher Bleck, President and Chief Executive Officer of Neothermia Corporation said, "This approval to expand the indications for the *en-bloc*® is a significant milestone for the Company and demonstrates wider application of this important technology. *en-bloc*® is the only non-surgical vacuum-assisted device that provides a large, intact specimen for pathology review. This allows for a more complete histologic review of the breast lesion."



Mr. Bleck continued, “More than an estimated 1.5 million breast biopsies are performed in the U.S. each year. Within this population, we expect the new indications to result in increased usage of the system, as it provides physicians with a greater measure of flexibility in removing and diagnosing suspicious lesions of the breast. The new indications will also provide a welcome alternative to patients with benign lesions, who can now have the entire lump removed with the non-invasive *en-bloc*® system, versus undergoing either core biopsy or an open surgical procedure.”

Dr. Larry Killebrew, Medical Director at The Oklahoma Breast Care Center, noted, “I have used the *en-bloc*® Biopsy System in more than 2,500 patients to date, and have found it to be an excellent tool in the diagnosis of questionable breast lesions. I appreciate the ability of the *en-bloc*® to remove more intact tissue from the region of the suspicious lesion, thereby providing superior diagnostic accuracy than percutaneous core biopsy would, and reducing the potential for procedural sampling error. The expanded indications for use of the *en-bloc*® will give me and my patients greater choice in the management of their conditions.”

About Neothermia Corporation

Founded in 1998, and based in Natick, Massachusetts, Neothermia is a privately held company focused on the design, development and marketing of innovative, minimally invasive systems for the volumetric excision of tissue for diagnostic and therapeutic applications in select cancer markets. The Company's lead product, the *en-bloc*® Biopsy System, received marketing clearance from the Food and Drug Administration in June 2001. Initial products are targeted at breast biopsy and tumor excision.

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