American Society for Laser Medicine and Surgery
31st ASLMS Annual Conference, April 1-3, 2011

ABSTRACT #79

A MULTI-CENTER EVALUATION OF THE MIRADRY SYSTEM TO TREAT SUBJECTS WITH AXILLARY HYPERHIDROSIS

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Background: A third generation microwave-based device has been developed to treat axillary hyperhidrosis by selectively heating the interface between the skin and underlying fat where the sweat glands reside.

Study: Thirty-one (31) adult subjects were enrolled in this multi-center, single-group study. All subjects had primary axillary hyperhidrosis evidenced by Hyperhidrosis Disease Severity Scale (HDSS) ratings of 3 or 4 and a gravimetric sweat assessment of at least 50mg in each axilla (in 5 minutes). Subjects were excluded if they had surgery for axillary hyperhidrosis or botulinum toxin injections in the axillae in the last 12 months. All subjects had between one and three treatment sessions over a 6-month period to fully treat both axillae. Local anesthetic was used for pain management. Follow-up visits between and after treatments measured effectiveness by collecting HDSS scores and gravimetric assessments at approximately 30-day intervals. Subject safety was assessed at each visit. Subjects will be followed for 12 months after all treatment sessions are complete.

Results: The mean age of enrolled subjects was 33 (range 18–65); 74% were female; mean BMI was 24.8. Efficacy measurements for the 21 subjects that had a visit 30 days after their second treatment session show 100% with HDSS scores of 1 or 2 and gravimetric assessments show 86% have had at least a 50% reduction in axillary sweat compared to baseline (while the median reduction was 90%). Regarding safety, all subjects experienced transient effects in the treatment area such as swelling, discomfort or numbness. As of the time of this report, the most common adverse event (n = 8 subjects) has been the presence of discrete, localized numbness in the arm that appears to be resolving.

Conclusion: The device tested provides an efficacious treatment for axillary hyperhidrosis. Further follow-up for safety and efficacy duration is planned.