**ABSTRACT**

**BACKGROUND:** Imiquimod is an immune response modifier that up-regulates cytokines and has been shown in clinical studies to reduce or clear basal cell carcinoma tumors when applied topically.

**OBJECTIVE:** The objectives were to evaluate the efficacy of 5% imiquimod cream in treating basal cell carcinoma preceding excision by Mohs micrographic surgery and to determine if reflectance-mode confocal microscopy is useful to establish the need for surgical intervention after imiquimod treatment.

**METHODS:** Subjects applied study cream to one biopsy-confirmed basal cell carcinoma tumor 5 x/week for 2, 4, or 6 weeks in this vehicle-controlled, double-blind study. Confocal microscopy was used for the 6-week treatment group to examine the target tumor area at each interval visit and immediately before Mohs micrographic surgery. After the Mohs micrographic surgery excision, the tissue was evaluated histologically, and the excision area was measured. Confocal microscopy readings were correlated to the histologic diagnosis.

**RESULTS:** Tumors cleared or the target tumor area was reduced in subjects in the 4- and 6-week dosing regimens. Confocal microscopy assessments correlated well with the histologic diagnosis.

**CONCLUSION:** Imiquimod improved excision results relative to vehicle when used for treating basal cell carcinoma before Mohs micrographic surgery. Confocal microscopy assessments correlated well with tumor response to therapy, suggesting that confocal microscopy may help determine the need for surgery.