Official title of study: UCI 14-92 / HS #2015- 1889: Phase IV Study of Daylight Photodynamic Therapy with Aminolevulinic Acid for Actinic Keratoses

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Protocol/Methods:

The study was designed prospectively to have 90% power to detect a 50% change in number of AKs. The study was approved by the University of California Institutional Review Board. A total of 30 patients were recruited from July 2015-October 2016 at the University of California, Irvine Department of Dermatology. Two patients were lost to follow up. Study inclusion criteria were age >18 years old with >10 actinic keratoses measuring >3mm each on the face or scalp. Exclusion criteria were history of photosensitive skin disorder, current pregnancy, or use of topical or oral retinoids, imiquimod, ingenol mebutate, fluorouracil, or photosensitizing medications in the past 3 months prior to PDT or during the 6 month study period. Patients were also excluded if the weather was rainy on the intended day of treatment.

Patients were instructed to wash their faces using a washcloth with warm, soapy water for 5 minutes in order to remove excess oil and improve drug penetration and then gently curetted with a 4mm non-disposable curette.

After curettage, the ALA (Kerastick®, DUSA) was applied first as spot treatment to the individual lesions and then as field treatment to the entire treatment area. Following ALA application, an avobenzone-containing chemical sunscreen was applied. The chemical sunscreen was utilized to block ultraviolet light (and possible sunburn from daylight exposure) while allowing wavelengths above 400nm to pass through and activate the PpIX.

After application patients were sent outdoors or home with a handheld luxometer (Suncheck Instruments, Model HS1010) and detailed written instructions. All patients were instructed to begin their daylight exposure within 30 minutes of ALA application and to remain in the daylight for 2 hours. We specifically asked patients to be in a shaded area “where you can see the sky but not the sun.” During daylight exposure, patients recorded pain (scale of 0-10), lux, the weather (raining, cloudy, partly cloudy, sunny) at times 0, 1 hour, and 2 hours, and patient

satisfaction (not satisfied, slightly satisfied, moderately satisfied, or very satisfied). After daylight exposure all patients were instructed to apply physical sunscreen with titanium or zinc oxide and a wide brimmed hat in order to block visible light and prevent further PPIX activation. The patients were not instructed to wash off the ALA afterward. They were instructed to go indoors for the following 48 hours. All patients were given prophylactic valacyclovir 500 mg BID for 7 days to prevent herpes simplex reactivation and possible eczema herpeticum.

Patients were evaluated and photographed at time 0 days, 3 days, 3 months, and 6 months after treatment and AK counts were performed at 0 days, 3 months, and 6 months. Summary statistics were calculated and a Pearson correlation coefficient test was performed (Stata/IC, Version 15) to assess the relationship between lux received and AK count at 6 months.