



INNOVATION IN PHOTODYNAMIC THERAPY

## **DUSA Pharmaceuticals, Inc.**

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### **INDEPENDENT STUDY RESULTS PRESENTED AT ASDS ANNUAL MEETING SHOW THAT DUSA'S LEVULAN® KERASTICK® PLUS INTENSE PULSED LIGHT (IPL) IMPROVES PHOTODAMAGED SKIN MORE THAN IPL ALONE**

**Wilmington, Massachusetts, October 4, 2004.** DUSA Pharmaceuticals, Inc. (NASDAQ NMS: DUSA) is pleased to report that at the annual meeting of the American Society for Dermatologic Surgery in San Diego, held September 30<sup>th</sup> to October 3<sup>rd</sup>, 2004, an independent investigator group presented the results of the first prospective, randomized, controlled, split face clinical study using the Levulan® (aminolevulinic acid HCl) Kerastick® together with intense pulsed light (IPL) for the treatment of photoaging. DUSA provided Levulan and financial support to the investigator group.

In the 20 patient study (a), led by renowned laser expert Dr. Jeffrey S. Dover of SkinCare Physicians of Chestnut Hill, MA, patients received a series of 3 split-face IPL treatments 3 weeks apart, in which half of the face was pretreated with the Levulan Kerastick followed in 45 plus or minus 15 minutes by IPL treatment, while the other half of the face was treated with the same doses of IPL alone. Each patient then received 2 additional full face IPL alone treatments 3 weeks apart, since the standard of care in non-ablative photorejuvenation had been 5 treatments with IPL alone. Patients were assessed by a blinded investigator for global photodamage, fine lines, mottled pigmentation, tactile roughness and sallowness prior to each treatment and 4 weeks after the final treatment. Pre-treatment with Levulan resulted in statistically significant improvement in global scores for photoaging (80% vs. 50%, p less than 0.02), and mottled pigmentation (95% vs. 65%, p less than 0.02). Pre treatment with Levulan also resulted in a significantly greater reduction of mottled pigmentation and fine lines to low or imperceptible levels (p less than 0.001 and p less than 0.01 respectively). Both the investigator cosmetic evaluations and the subject satisfaction scores were significantly better for the Levulan plus IPL treated sides. The investigators found no difference in the side effect profile with or without Levulan pretreatment, and noted that both treatments were well tolerated. They also noted that no patients dropped out of the study.

The investigators concluded "The adjunctive use of ALA in the treatment of facial photoaging with IPL provides significantly more improvement in global photodamage, mottled pigmentation, and fine lines than treatments with IPL alone, without a significant increase in side effects. This combination treatment allows physicians to provide better results, with higher patient satisfaction."

Facial photoaging or photodamage is a common cosmetic problem seen in light-skinned individuals with years of significant exposure to the sun. Signs of facial photodamage include increasing skin sallowness, roughness, fine wrinkling and mottled pigmentation. Current treatments for this condition include laser resurfacing, nonablative photorejuvenation using laser and non-laser light sources, dermabrasion and chemical peels. Results from earlier published independent investigator studies reported that photodynamic therapy (PDT) carried out using Levulan plus IPL helped to resolve

certain signs of facial photodamage (b). However, no controlled split-face studies versus IPL alone have been previously reported.

D. Geoffrey Shulman, MD, DUSA's President and CEO, stated "We are very pleased with the positive results of this independent study in the treatment of photodamaged skin, in which 3 treatments with Levulan plus IPL (plus 2 IPL alone) were compared to 5 treatments with IPL alone, which until now has been the standard of care in non-ablative photorejuvenation. DUSA hopes to corroborate and extend these results with DUSA's ongoing Phase II multi-center split-face photodamaged skin study utilizing 3 light sources (IPL, long pulse dye laser and DUSA's BLU-U®) with and without Levulan.

The ASDS meeting also included at least 13 other scientific presentations focused on PDT, including a full session called 'Expanding the Uses of Topical Photodynamic Therapy'. DUSA was also well represented at the technical exhibits, with a full complement of sales and marketing staff to answer questions and engage in discussions with the large number of physicians showing interest in our therapy."

(a) Bhatia, AC, Dover, JS, Stewart, B and Arndt, K. Adjunctive use of topical Aminolevulinic acid with Intense Pulse Light in the Treatment of Photoaging. ASDS 2004.

(b) Original Investigator Reports:

1. Avram D, Goldman M. Effectiveness and safety of ALA-IPL in treating actinic keratoses and photodamage. *J Drugs Dermatol* 2004; **3**: S36-S9.
2. Ruiz-Rodriguez R, Sanz-Sanchez T, Córdoba S. Photodynamic photorejuvenation. *Dermatol Surg* 2002; **28**: 742-4.

DUSA Pharmaceuticals, Inc. is a biopharmaceutical company engaged primarily in the development and marketing of Levulan Photodynamic Therapy (PDT) and Photodetection (PD) for multiple medical conditions, with a primary focus on dermatology. PDT and PD utilize light-activated compounds to induce a therapeutic or detection effect. DUSA is a world leader in topically or locally applied PDT and PD. DUSA maintains offices in Wilmington, MA, Valhalla, NY and Toronto, Ontario.

Except for historical information, this news release contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to DUSA's hope to corroborate and extend the results of the investigators' study in DUSA's own ongoing Phase II study. The risks and factors that may cause differing results include the regulatory process, the results of ongoing clinical studies, continued funding for the on-going and future studies, and other risks identified in DUSA's SEC filings from time to time.

For further information contact: D. Geoffrey Shulman, MD, President & CEO or Shari Lovell, Director, Shareholder Services Tel: 416.363.5059 Fax 416.363.6602 or visit [www.dusapharma.com](http://www.dusapharma.com)