actinic keratoses of the face and scalp. This table lists the two pivotal trials. Eight centers in the United States participated in each of these studies. After qualifying for the study, subjects were randomized in a 3:1 ratio to receive either Levulan or vehicle applicators, respectively.

In our review, the primary endpoint parameter was based on the percent of subjects who were completely cleared of all their targeted lesions at Week 8, based on an intent-to-treat population. At Week 8 if an observation was missing, it was considered a failure. In addition to the per-subject analysis, a per-lesion evaluation was performed. These analyses were done based on per-protocol instead of intent-to-treat.

In order for this drug product to prove efficacy, the sponsor has to demonstrate the superiority of Levulan solution to its vehicle in each of these two studies separately. I will be referring to these studies as Study 018 and 019 throughout this presentation.

Next slide, please.

Study 018, a total of 117 subjects from eight centers were enrolled into Study 018, where 88 subjects were randomized into the Levulan and 29 into the vehicle arm. No statistical differences were found between the two

treatment arms in regard to the demographics and baseline characteristics of the subjects.

And to answer your question, Dr. Lavin, that's showing the distribution of lesions or subjects for face and scalp separately. I think that was one of your questions.

DR. LAVIN: I asked within face and scalp, not overall.

MS. FARR: Next slide, please.

This table summarizes the results of the analysis for the primary endpoint variable, which was the percentage of subjects who had 100 percent of their lesions cleared. As is seen in this table, highly significant results were observed when Levulan was compared to the vehicle arm relative to the rate of complete clearance.

Next slide, please.

This table summarizes the results of the analysis for the primary endpoint variable for subjects who had 75 percent or more of their lesions cleared, and as you can see in this table, highly significant results were observed when Levulan was compared to the vehicle arm.

Next slide, please.

This is Study 019. A total of 126 subjects from eight centers were enrolled into Study 019, where 90

subjects were randomized into the Levulan and 33 into the vehicle arm. No statistical differences were found between the two treatment arms in regard to the demographics and baseline characteristics of these subjects.

Next slide.

This table summarizes the results of the analysis for the primary endpoint variables for subjects who had 100 percent of their lesions cleared for Study 019. As is shown in this table, highly significant results were observed when Levulan was compared to the vehicle arm relative to the complete clearance.

Next slide, please.

This table shows the result of the analysis for subjects who had 75 percent or more of their lesions cleared for Study 019. Again, as we can see, highly significant results were observed when the two arms were compared to each other.

Next slide, please.

Now, as I mentioned previously, the lesion analyses were based on per-protocol. Now I'm looking at the total number of lesions of the patients. This is Study 018. A total of 803 lesions were under the study. Of these, the data was available for only 784 at Week 8. This table gives the response rate for these lesions. Highly

significant results were observed when Levulan was compared to the vehicle arm.

Next slide, please. Thank you.

Now the lesion analysis for Study 019. A total of 1,086 lesions were under the study, and of those, the data was available for 1,066 at Week 8. This table gives the rate of response for these lesions, and, again, as we can see, highly significant results were observed when Levulan was compared to the vehicle arm.

Next slide, please.

Now, this is the subset analysis. The two data sets were merged, and subset analysis was done based on lesion counts by gender, age category, which was younger than 60 or 60 and older, skin type, and the location of the lesions, which was face or scalp. Highly significant results were observed in each one of these subcategories.

Next slide, please.

Conclusions. The results of the analysis of efficacy of the two studies, Study 018 and 019, demonstrate that Levulan Kerastick topical solution, 20 percent, is statistically significantly better than vehicle in the treatment of multiple actinic keratosis of the face and scalp.

Now Dr. Okun will continue this presentation.

DR. OKUN: This slide shows a flow chart reflecting the patient outcomes from pooled pivotal trials. It's a little complicated to look at. We'll just take a few minutes to go over it, because there is actually a great deal of information here.

Firstly, I should mention that the outcomes from the pivotal trials were pooled in this flow chart merely for illustrative purposes. This approach is justifiable because the two trials had identical protocols, and it's worth noting that the results from the two trials were not pooled in the review process. Each trial standing on its own achieved clinical and statistical significance.

DR. DRAKE: Excuse me. Could I ask you to bring the mike a little closer?

DR. OKUN: I apologize. I'll try and be more conscious of that.

Only two patients in the active treatment arm were discontinued due to adverse events experienced during light treatment. Five others in the active treatment arm and three in the vehicle arm were lost to follow-up.

A couple of points suggest themselves from this slide. First of all, clearly the majority of patients who were treated with Levulan experienced 100 percent complete response by Week 8. You have 180 being treated here, and

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