A MULTICENTER, INVESTIGATOR-BLIND, RANDOMIZED STUDY
WITH BENZOYL PEROXIDE/CLINDAMYCIN: FINAL DATA FROM
COMPARING A NOVEL SOLUBILIZED BENZOYL PEROXIDE GEL
WITH BENZOYL PEROXIDE/CLINDAMYCIN

INTRODUCTION
A novel solubilized 5% BPO gel has recently become available as a treatment for acne vulgaris——both as a stand-alone acne system (as part of a 3-step acne system) or in conjunction with a proprietary cleanser and barrier cream containing 2% salicylic acid. In all formulations of BPO, the lipophilic ester and sodium percarbonate penetration of BPO can be suboptimal because the molecule is poorly soluble and can exist as microcrystalline versus diamine which may exceed that of BPO filmolates. Current, the solubilized BPO formulation aims to improve the solubilization in order to promote greater penetration and lower and greater potency of BPO into the follicles. We have compared the efficacy and tolerability of the solubilized BPO formulation against a leading 5% BPO microcrystalline prescription product in a multicenter investigator-blinded study. An initial 4-week start from the study has been presented previously. Patients have been subsequently enrolled into the study and the period of treatment has been extended to 12 weeks. Results have been derived from both study analyses are reported.

METHODS
Study design
A multicenter, investigator-blind, randomized, split-face study was conducted.

Key inclusion criteria
• Facial cosmetic procedure in the preceding 6 months
• Allergy to benzoyl peroxide, clindamycin, lincomycin, salicylic acid, and other ingredients
• Willing to refrain from excessive exposure to the sun and the use of products around the lips and eyes (however, oil-free non-comedogenic make-up, mascara, moisturizers, sunscreens, fragrances, aftershaves, and make-up were allowed)

Key exclusion criteria
• Patients were randomly assigned to apply one of the following to one side of their face and the other to the contralateral side of their face: twice daily for 12 weeks:

  - Solubilized 5% BPO gel
  - 5% BPO microcrystalline clindamycin (other than acne) that could interfere with study evaluations
• Patients were instructed to avoid applying the test products around the lips and eyes, and were advised to use a non-comedogenic moisturizer with sunscreen; all patients were instructed to use sunscreen and protective clothing

Table 1: Scales used to evaluate tolerability parameters.

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
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<tbody>
<tr>
<td>Erythema</td>
<td>Intensity of redness, easily warm to the touch</td>
</tr>
<tr>
<td>Dryness</td>
<td>Roughness and dryness</td>
</tr>
<tr>
<td>Peeling</td>
<td>Noticeable peeling sensation</td>
</tr>
<tr>
<td>Stinging/burning</td>
<td>Tingling/sting sensation</td>
</tr>
<tr>
<td>Itching</td>
<td>Noticeable itching</td>
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Delivered results
• 40% of patients had a more than 50% reduction in inflammatory lesion count (open comedones plus closed comedones)
• Inflammatory lesion count (papules plus pustules plus nodules) was reduced by a mean of 46% with BPO/clindamycin at weeks 1, 2, 3, 4, and 12 (P < 0.05, Figure 1).
• Between-group differences in inflammatory lesion count were significant at all timepoints (Figure 2). A P value of ≤ 0.05 was considered statistically significant.

RESULTS
Patient satisfaction
Patient satisfaction with the improvement in their acne was significantly higher with the solubilized BPO gel than with the BPO microcrystalline (Figures 4, 5, 6, 7, 8). The patients had a more than 15% and 54% were satisfied. They were predominantly:

• Caucasian (71%); Caucasian, 6% Caucasian Hispanic/Latino, 14% Black, 1% Asian, 6% other

EFFICACY
The solubilized BPO gel resulted in a significantly greater reduction in inflammatory lesion count than BPO microcrystalline at weeks 1, 2, 3, 4, and 12 (P < 0.05, Figure 1).

At week 12, the inflammatory lesion count (Figure 2) was reduced by a mean of 12% with the solubilized BPO gel (P < 0.05 versus BPO microcrystalline). BPO/clindamycin (N = 65)Solubilized BPO (N = 65)

<table>
<thead>
<tr>
<th>Week</th>
<th>Median change from baseline in inflammatory lesion count</th>
<th>P value</th>
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<tbody>
<tr>
<td>1</td>
<td>-64%</td>
<td>≤ 0.05</td>
</tr>
<tr>
<td>2</td>
<td>-46%</td>
<td>≤ 0.05</td>
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Both groups showed comparable reductions in the inflammatory lesion count at all timepoints (Figures 4-8). It is also possible that the unique solvent technology used in the BPO formulation could play a role.

CONCLUSIONS
In the study, the BPO gel was free of advantages of comedone-related irritations. First, significantly greater reductions in inflammatory lesion count may be evident after only 4 weeks of treatment (and speed of improvement is very important to patients). Second, the clinical advantages of the solubilized 5% BPO gel is achieving a comparable reduction in inflammatory lesion count and a significantly greater reduction in non-inflammatory lesion count is achieved in the IVS. The IVS is a subject of validation.

REFERENCES
1. Introduction to Sub-Clinical vs Genenetic vs.
2. Clinical Trials of B - D - Preclinical Development.
3. Clinical Trials of B - D - Preclinical Development.
4. Supported by OMP, Inc.

DISCLOSURES
Supported by OMP, Inc.