Efficacy and Safety of a Fixed-Dose Clindamycin Phosphate 1.2%, Benzoyl Peroxide 3.1%, and Adapalene 0.15% Gel for Randomized-Phase 2 and Phase 3 Studies of the First Triple-Combination Drug

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SYNOPSIS AND OBJECTIVE

A three-pronged approach to acne treatment—combining an antibiotic, anti-inflammatory agent, and retinoid in a single formulation—has been investigated as a means to provide greater efficacy than single-dose treatments while potentially reducing antibiotic resistance.

Clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15% (IDP-126) gel is the first triple-combination, fixed-dose topical acne product available for development and this product addresses the major pathophysiological abnormalities in acne patients (Stein-Gold AJCD 2022).

The objective of these studies was to evaluate the efficacy, safety, and tolerability of IDP-126 in phase 2 and 3 studies of patients with moderate-to-severe acne.

STUDY TREATMENTS AND PARTICIPANTS

12-Week Studies of IDP-126 Gel

Randomized, Double-Blind, Active/Vehicle-Controlled Treatment

- **baseline**
- **week 12**

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDP-126 Gel</td>
<td>141</td>
<td>110</td>
</tr>
<tr>
<td>BPO/ADAP Gel</td>
<td>149</td>
<td>109</td>
</tr>
<tr>
<td>CLIN/BPO Gel</td>
<td>144</td>
<td>110</td>
</tr>
<tr>
<td>CLIN/ADAP Gel</td>
<td>146</td>
<td>109</td>
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<tr>
<td>VEH</td>
<td>60</td>
<td>51</td>
</tr>
</tbody>
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**ALL STUDIES**

Key Eligibility Criteria:
- Age (11 years)
- Baseline IL at least 1 (on a scale of 0–160)
- No inflammatory lesions: 30–100
- None or redness: 30–150

**Baseline Demographics/Characteristics**
- Mean age ranged from 19 (2–21) years across all studies
- Most participants were female, white, and non-Hispanic with a mean 70% reduction in inflammatory counts

**Efficacy**

- **Phase 2 Study 1 (NCT03214625)**
- **Phase 2 Study 2 (NCT03214626)**
- **Phase 3 Study 1 (NCT03210588)**
- **Phase 3 Study 2 (NCT03210589)**

**Results:**

- **Phase 2 Study:**
  - **Change from baseline in inflammatory lesions at Week 12 (ITT Populations)**
  - **Noninflammatory Lesions**
  - **All Studies**

**Safety: AEs and TEAEs**

- **Most common treatment-related TEAEs**
- **Less than 4% of participants discontinued studies/treatment due to AEs**
- **Most TEAEs were mild or moderate severity (data not shown)**

**Author Disclosures**

- The innovative fixed-dose, triple-combination IDP-126 gel was efficacious and well tolerated in clinical studies including children, adolescents, and adults with moderate-to-severe acne
- In all three studies at week 12, ~50% of participants achieved treatment success
- IDP-126 resulted in over 70% reductions of inflammatory and noninflammatory lesions at week 12
- To our knowledge, observed acne improvements in these studies with IDP-126 were greater than any FDA-approved topical acne treatment, though patient populations may differ across studies

CONCLUSIONS

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