Dermal Irritation, Sensitization, and Safety of Fixed-Dose Triple-Combination Clindamycin Phosphate 1.2%/Benzoyl Peroxide 3.0%/Adapalene 0.15% Gel in Healthy Participants

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BACKGROUND AND OBJECTIVES
To assess dermal irritation/sensitization and safety of IDP-126 gel in two phase 1 studies.

METHODS
Two phase 1, randomized, evaluator-blinded, within-participant, dermal safety studies enrolled healthy participants aged 18 years (Figure 1). To compare idemix of IDP-126 gel and commercially available BPO 2.5%/ adapalene 0.15% gel in one phase 1 study of healthy participants randomized to each other and/or an antibiotic (ie, allergic potential) in healthy participants.

RESULTS
Participants
– 279 participants were randomized.
– RPT populations: safety, N=234; 4 (1.7%)
– Patches were applied to participants’ skin.
– To assess dermal irritation/sensitization.
In both studies, the mean age of participants was 55 years, and the majority were female (RPT: 71.4%; CIPT: 77.1%; BPO 2.5%/ADAP: 68.2%; and non-Hispanic, 99.3%, 91%, with a Fastderm score of 80.0%)

Dermal Irritation and Sensitization
Overall, irritation with IDP-126 was mild and not clinically significant.

IDP-126, vehicle gel, and saline 0.9% were all classified as not causing clinically significant irritation.

To determine irritation classification of each treatment, a normalized total score for each patch was calculated by multiplying the mean total irritation score by a factor of 10.
– IDP-126 demonstrated good safety and no clinically significant irritation.
– No evidence of irritation.
– Overall, IDP-126 demonstrated good safety and no clinically significant irritation.

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CONCLUSIONS
In two phase 1 studies, fixed-dose, triple-combination IDP-126 polymeric mesh gel had moderate irritancy and no confirmed sensitization (ie, allergic potential) in healthy participants.

Additionally, IDP-126 gel demonstrated significantly less irritation versus commercially available, branded BPO 2.5%/adapalene 0.15% gel.

IDP-126 was well tolerated, with most TEAs of mild-moderate severity.

Overall, IDP-126 demonstrated good safety and tolerability, mirroring the phase 2 and phase 3 study results.

REFERENCES

AUTHOR DISCLOSURES
ZDA has received fees from Ortho Dermatologics. EAT has received speaker fees from Ortho Dermatologics, Regeneron, Sanofi, Verrica, and Pfizer. LSG has served as advisor, consultant, and investigator for Albick, dermAdapalene, Dermavant, Dermira, and Pacific Skin. TSC has served as advisor, consultant, and investigator for Albic, dermAdapalene, Dermavant, Dermira, and Pacific Skin. JLG has received speaking fees from Ferring, Johnson & Johnson, and Regeneron. JLS has served as advisor, consultant, and investigator for Albic, dermAdapalene, Dermavant, Dermira, and Pacific Skin. JAZ has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. LT has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. ETJ has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. JDC has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. HLF has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. JFC has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin. ATK has served as advisor, consultant, and investigator for AbbVie, Allergan, Dermavant, Dermira, and Pacific Skin.