Halobetasol Propionate 0.01% Lotion for Plaque Psoriasis: Epidermal Permeation, Efficacy, and Safety

Lawrence Green, MD[1]; Jerry Bagel, MD[2]; George Han, MD, PhD[3]; Abby Jacobson, MS, PA-C[4]; Martha L. Sikes, DMSc, MS, RPh, PA-C[4]

[1]Department of Dermatology, George Washington University School of Medicine, Washington, DC; [2]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ; [3]Icahn School of Medicine at Mount Sinai, New York, NY; [4]Ortho Dermatologics, Bridgewater, NJ

OBJECTIVE

- **To summarize the in vitro epidermal permeation of halobetasol propionate (HP) 0.01% lotion and its clinical efficacy and safety in participants with plaque psoriasis**

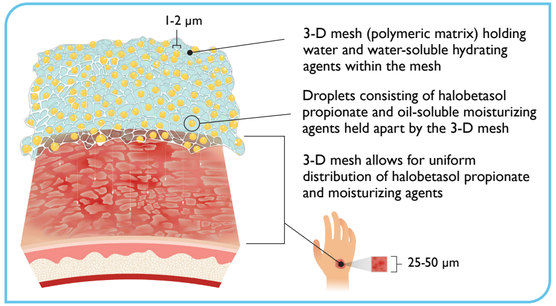
CONCLUSION

- **A low-concentration HP 0.01% lotion formulation demonstrated >3.5-fold higher epidermal penetration of the active ingredient than HP 0.05% cream**
  - **The polymeric emulsion 0.01% lotion formulation allows for more effective delivery of HP, even at one-fifth the concentration of HP 0.05% cream**
- **HP 0.01% lotion was more efficacious than vehicle in the treatment of moderate-to-severe plaque psoriasis, had a favorable safety profile over 8 weeks of once-daily use, and led to no treatment-emergent adverse event (TEAE) reports of skin atrophy or folliculitis**
- **Once-daily HP 0.01% lotion is an efficacious and safe option for psoriasis treatment beyond the 2 to 4 weeks of continuous use recommended for other topical corticosteroids**

SYNOPSIS

- Topical corticosteroids are the mainstay of psoriasis treatment and can be used as monotherapy or in combination with other treatments[1]
- However, the use of superpotent topical corticosteroids, such as HP, is generally limited to 2 to 4 weeks as monotherapy to mitigate the risk of cutaneous side effects[1,2]
- A lower-dose formulation of HP 0.01% lotion was developed using polymeric emulsion technology, which allows for up to 8 weeks of continuous once-daily use (Figure 1)

Figure 1. Polymeric emulsion lotion technology.



METHODS

Percutaneous Absorption Study

- Epidermal deposition of HP 0.01% lotion and HP 0.05% cream was compared in an in vitro percutaneous permeation study
- Approximately 5 mg/cm^2 of each formulation (clinically relevant dose) was applied to dermatomed cadaveric human tissue from 1 female donor
- After 24 hours, HP concentrations were determined with liquid chromatography–mass spectrometry

Phase 3 Studies

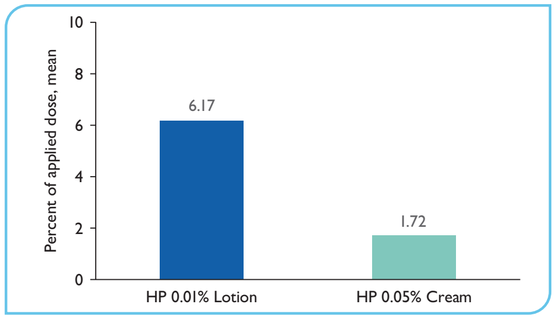
- In two phase 3 randomized, double-blind, vehicle-controlled studies (NCT02514577, NCT02515097), adult participants with psoriasis were randomized (2:1) to receive HP 0.01% or vehicle lotion once daily for 8 weeks, with a 4-week posttreatment follow-up[3]
  - At baseline, participants were required to have an Investigator's Global Assessment (IGA) score of 3 (moderate) or 4 (severe) and affected body surface area (BSA) of 3% to 12%
  - In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal cleaning/moisturizing of the skin
- Data from the 2 studies were pooled for analysis; efficacy assessments included treatment success (percentage of participants with ≥2-grade reduction in IGA score and a score of 0 [clear] or 1 [almost clear]) and reduction in affected BSA
- Safety and tolerability assessments included TEAEs

RESULTS

Epidermal Permeation (In Vitro)

- HP 0.01% lotion demonstrated superior permeation efficiency over 0.05% cream, with a >3.5-fold higher percentage of the applied dose measured in the epidermis (Figure 2)

Figure 2. Epidermal levels of HP following 24 hours of topical exposure.



Mean of 10 tissue samples shown. HP, halobetasol propionate.

Phase 3 Studies

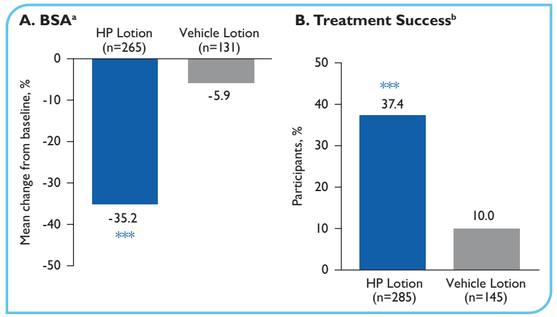
Efficacy

- In the phase 3 studies, 430 adults were randomized to HP lotion (n=285) or vehicle lotion (n=145)
- HP 0.01% lotion was statistically superior to vehicle at week 8 in percent reduction from baseline in affected BSA and percentage of participants achieving treatment success (Figure 3)

Adverse Events

- Rates of TEAEs through week 8 were similar for participants treated with HP 0.01% lotion and those treated with vehicle, as were TEAE severity and incidence of treatment-related TEAEs (Figure 4)

Figure 3. Affected BSA reduction **(A)** and treatment success **(B)** at week 8.



***P<0.001 vs vehicle. BSA, body surface area; HP, halobetasol propionate; IGA, Investigator's Global Assessment. [a]No imputation of missing data. [b]Defined as ≥2-grade reduction from baseline in IGA score and a score of "clear" or "almost clear." Values have been adjusted for multiple imputation.

- Treatment-related TEAEs with HP 0.01% lotion were local application site reactions, none of which occurred in more than 2 participants (Table 1)

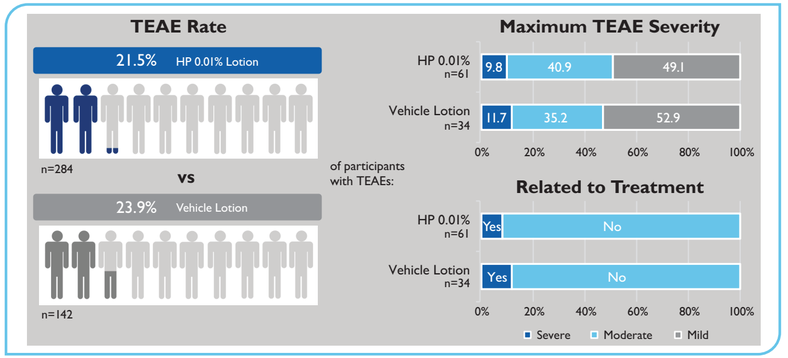
Table 1. Treatment-related TEAEs Through Week 8

TEAEs, n (%)	HP 0.01% Lotion (n=284)	Vehicle Lotion (n=142)
Application-site dermatitis	2 (0.7)	0
Application-site pruritus	1 (0.4)	1 (0.71)
Application-site infection	1 (0.4)	0
Application-site discoloration	1 (0.4)	0
Application-site pain	0	2 (1.4)
Psoriasis	0	1 (0.7)
Application-site cellulitis	0	1 (0.7)
Application-site abscess	0	1 (0.7)

HP, halobetasol propionate; TEAE, treatment-emergent adverse event.

- There were no TEAE reports of skin atrophy or folliculitis with HP treatment; there was 1 TEAE of telangiectasia in the HP lotion group that was deemed unrelated to treatment

Figure 4. Overview of TEAEs through week 8.



HP, halobetasol propionate; TEAE, treatment-emergent adverse event.

Acknowledgments: Medical writing support was provided by Medthink SciCom (Cary, NC) with financial support from Ortho Dermatologics; Ortho Dermatologics is a division of Bausch Health US, LLC.

Disclosures: LG has served as a consultant, speaker, and/or investigator for AbbVie, Amgen, Arcutis, Celgene, Dermavant, Janssen, Lilly, MC2, Novartis, Ortho Dermatologics, Sienna, Sun Pharma, and UCB. **JB** is an investigator and speaker for Ortho Dermatologics. **GH** is or has been an investigator, consultant/advisor, or speaker for AbbVie, Athenex, Boehringer Ingelheim, Bond Avillion, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, MC2, Novartis, Ortho Dermatologics, PellePharm, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. **AB** and **MLS** are employees of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

Prior Presentation: Data in this poster were previously presented at the Winter Clinical Dermatology Conference; January 16-24, 2021; virtual.

References: 1. Elmets et al. *J Am Acad Dermatol.* 2021;84:432-470. **2.** Bagel et al. *Cutis.* 2020;105:92-96;E94. **3.** Sugarman et al. *Cutis.* 2019;103:111-116.

Presenting Author: Lawrence Green, MD; drgreen@looking-younger.com

Presented at Winter Clinical Dermatology Conference® • January 13-18, 2023 • Kohala Coast, HI

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