IL-23, 33 inhibitors show promise in phase 3

Kenneth B. Gordon, MD: “We saw 75% of patients achieving PASI 90 versus 5% on placebo, and 88% sPGA clear or almost clear compared to 8%.”

Data from two phase 3 trials support the efficacy and safety of IL-23 and IL-33 inhibitors in moderate-to-severe plaque psoriasis. Risankizumab showed superiority to both placebo and ustekinumab over 52 weeks while guselkumab showed similar responses in retreatment, as it did in continuous treatment. Both trials were presented during Saturday’s “Late-breaking Research: Clinical Trials” (F061).

Two trials compared IL-23 inhibitor risankizumab against placebo and ustekinumab over 52 weeks. Patients in the placebo arm were crossed over to risankizumab after 16 weeks. The primary endpoints were PASI 90 and sPGA 0/1 while 15 secondary endpoints assessed results at specific time points during the 52-week study. Risankizumab met all endpoints.

“We saw 73% of patients achieving PASI 90 versus 5% on placebo, and 88% sPGA clear or almost clear compared to 8%,” said lead author Kenneth B. Gordon, MD, Thomas J. Russell Family/Milwaukee Dermatologists professor and chair of dermatology at the Medical College of Wisconsin. “We saw 48% PASI 90 from ustekinumab. We saw a similar response in the risankizumab group versus 30% for ustekinumab.

Adverse events were similar for risankizumab and ustekinumab with no unexpected safety signals. The guselkumab data focused on VOYAGE 2 results of continuous treatment versus retreatment in patients who were taken off drug at 28 weeks and lost 50% or more of their PASI improvement. Two other arms of the study — placebo and adalimumab — were not included in the presentation.

Of patients who remained on treatment during the 76-week study, 86% showed PASI 90 or better. When patients were taken off drug, only 37% showed PASI 90 20 weeks later and 12% showed it at the end of the study 44 weeks later.

Patients who were randomly withdrawn from guselkumab and retreated showed a response similar to continuous treatment with 88% achieving PASI 90. “We know that if you withdraw from the drug, you open the door to the return of disease,” said lead author Kristian Reich, MD, Dermatolgikum Hamburg and SCIderm Research Institute in Hamburg, Germany.

“We saw that treating patients with guselkumab produces very similar responses as continuing treatment. We also saw that patients who maintained their PASI response after drug was withdrawn showed continuing suppression of IL-17A, IL-17F, and IL-22. Does this open the door to a true disease-modifying drug? I don’t know, but we saw a durable response even when patients stopped being treated.”

An open-label extension of the study to 100 weeks will be reported later.

“We know that if you withdraw from the drug, you open the door to the return of disease.”

— Kristian Reich, MD
Rapid Relief in Real Time

Get a closer look at clinically proven AmLactin® Rapid Relief, the only patented formula to combine our powerful Alpha-Hydroxy Therapy and three ceramides, for 24-hour relief from dryness.

See the difference on your own skin by visiting our booth.

SUNBURN ALERT: This product contains an alpha-hydroxy acid (AHA) that may increase your skin’s sensitivity to sunburn. Be sun smart: Use sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterward.
Meet your 2018 slate of candidates

The American Academy of Dermatology has selected its candidates in this year’s election. The Nominating Committee voted to present the following slate of candidates (listed in random order) to the membership for the 2018 Academy election of officers, directors, and Nominating Committee member representatives.

The election is open through Saturday, March 3. Vote online at www.aad.org/aadelection or from the 2018 AAD Meeting Mobile App.

Nominating Committee Member Representatives

Edward H. Yob, DO, FAAD
Wilma F. Bergfeld, MD, FAAD
Alexander Miller, MD, FAAD
Anthony M. Rossi, MD, FAAD
Cyndi Yag-Howard, MD, FAAD
Larry Green, MD, FAAD

Board of Directors

Bruce H. Thiers, MD, FAAD
Mark D. Kaufmann, MD, FAAD
Susan C. Taylor, MD, FAAD
Neal Bhatia, MD, FAAD

JAK inhibitors show promise for AD

A new class of oral agents may be on the way for atopic dermatitis (AD). Early trials of Janus kinase (or JAK) inhibitors show promise in moderate-to-severe disease. Prednisone is currently the only FDA-approved oral-systemic treatment for AD.

Upadacitinib, a once daily JAK1 inhibitor, showed good differentiation between doses of 7.5 mg, 15 mg, 30 mg, and placebo in a phase 2 trial. Mean EASI scores improved 25% for placebo versus 74.4% for the 30 mg dose over the 16-week trial. A 72-week extension will be reported later.

“Even the lowest dose gave us good EASI 90 results while 50% of patients on the highest dose showed EASI 90,” said Emma Guttman-Yassky, MD, PhD, Sol and Clara Kest professor of dermatology, Icahn School of Medicine at Mount Sinai Medical Center. “And we saw no serious adverse events.”

Dr. Guttman-Yassky also presented data showing strong patient-reported outcomes for baricitinib, a JAK1/2 inhibitor approved for rheumatoid arthritis in the European Union and Japan.

ASN002, a first-in-class JAK/SYK inhibitor, showed 50% EASI 75 during a 29-day proof-of-concept trial with no study-related adverse events, said Robert Bissonnette, MD, MSc, president of Innovaderm.

Emma Guttman-Yassky, MD, PhD, presented data showing strong patient-reported outcomes for baricitinib, a JAK inhibitor approved for rheumatoid arthritis abroad.

“Even the lowest dose gave us good EASI 90 results while 50% of patients on the highest dose showed EASI 90.” — Emma Guttman-Yassky, MD, PhD

FLU SEASON IS NOT OVER

If you feel flu symptoms, be smart — don’t stay in your hotel room or the convention center, seek medical attention.
DERMATOLOGY WORLD MEETING NEWS • SUNDAY • FEBRUARY 18, 2018

**SUNDAY**

7 a.m.-5:30 p.m.
AAD registration open
Location: Lobby D

8 a.m.-5 p.m.
AAD Resource Center open
Location: Hall A

8-11:30 a.m.
Plenary session
Location: Ballroom 20B

11-11:45 a.m.
Industry Expert Session
- COSENTYX® (secukinumab): A Comprehensive Approach to Treating Moderate to Severe Plaque Psoriasis
  Location: Exhibit Hall
  Hosted by Novartis Pharmaceuticals Corp.

12-1 p.m.
Unopposed exhibit time

1-4 p.m.
Resident Jeopardy (S037)
Location: Room 6D

1:30-2:15 p.m.
Industry Expert Sessions
- Novartis Pharmaceuticals Corp.
  Location: Exhibit Hall

7 p.m. (6:30 p.m. registration)
Industry Non-CME Programs
- Clinical Issues* in Severe Atopic Dermatitis: Debates and Discussions About Managing Moderate to Severe Disease
  Location: Hilton Bayfront, Indigo AB, EF
  Hosted by Integritas Communications.
  This activity is supported by an educational grant from Sanofi Genzyme and Regeneron Pharmaceuticals.

**TUESDAY**

7:30 a.m.-12:30 p.m.
AAD registration open
Location: Lobby D

8-10 a.m.
What’s New in Dermatology (S047)
Location: Room 6B

10:30 a.m.-12:30 p.m.
Therapeutic and Diagnostic Pearls (S068)
Location: Room 6B

**MONDAY**

7 a.m.-5:30 p.m.
AAD registration open
Location: Lobby D

8 a.m.-5 p.m.
AAD Resource Center open
Location: Hall A

9 a.m.-12 p.m.
Hot Topics (S048)
Location: Room 6D

10:30 a.m.-12:30 p.m.
Therapeutic and Diagnostic Pearls (S068)
Location: Room 6B

**EDUCATIONAL OBJECTIVES**

- Describe the pathophysiologic mechanisms and risk factors that contribute to atopic dermatitis development and persistence, with a focus on specific targets of current and emerging systemic treatments
- Assess patients with atopic dermatitis over time for uncontrolled symptoms, sleep disturbances, comorbid conditions, and treatment responses
- Describe the mechanistic rationale and clinical evidence for current and emerging biologic therapies in the treatment of moderate-to-severe atopic dermatitis
- Individualize long-term therapeutic regimens for moderate-to-severe atopic dermatitis to prevent exacerbations, manage comorbidities, maximize health-related quality of life, and minimize treatment-related side effects
- Communicate with patients and caregivers to improve their understanding of atopic dermatitis and the importance of treatment adherence and promote shared decision-making

**NEW AAD HONORARY MEMBERS**

This year, the AAD is honoring five physicians for their work in dermatology by naming them as AAD honorary members:
- Diane Baker, MD
- Suzanne Connolly, MD
- Mark Lebwohl, MD
- David McLean, MD
- John Voorhees, MD

**CLINICAL ISSUES IN ATOPIC DERMATITIS**

**DEBATES & DISCUSSIONS ABOUT MANAGING MODERATE-TO-SEVERE DISEASE**

**SUNDAY**

6:30 p.m.—7:00 p.m.
Registration and dinner

7:00 p.m.—9:00 p.m.
Educational Activity

**HILTON BAYFRONT**

Indigo Ballroom AB, EF • San Diego, California

**AMY S. PALLER, MD**

**JONATHAN SILVERBERG, MD, PhD, MPH**

**ERIC L. SIMPSON, MD, MCR**

Office of Continuing Medical Education

Integritas Communications
FIRST & ONLY SPRAYABLE OINTMENT

Effective, long-lasting relief of dry, rough skin in patients with xerosis

<table>
<thead>
<tr>
<th>% SUBJECTS IMPROVED</th>
<th>96% dryness</th>
<th>91% scaling</th>
<th>80% cracks</th>
</tr>
</thead>
</table>

The lightweight lotion that WORKS LIKE A CREAM

Superior hydration with daily use vs CeraVe® Moisturizing Cream

Study design: Double-blind, bilateral, clinical comparative study to assess the efficacy of Eucerin Advanced Repair Lotion vs CeraVe Moisturizing Cream (N=35). Statistically significant difference between treatments, p<0.05.
San Diego snaps

Daily highlights of the 2018 AAD Annual Meeting

Saturday was bustling at the San Diego Convention Center with attendees networking and visiting with colleagues while attending sessions and visiting some of the 400 exhibitors in the Exhibit Hall.
For the treatment of mild-to-moderate atopic dermatitis (AD) in patients 2 and older

**INDICATION**

EUCRISA is indicated for topical treatment of mild-to-moderate atopic dermatitis in patients 2 years of age and older.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**

EUCRISA is contraindicated in patients with known hypersensitivity to crisaborole or any component of the formulation.

**Warnings and Precautions**

Hypersensitivity reactions, including contact urticaria, have occurred in patients treated with EUCRISA and should be suspected in the event of severe pruritus, swelling and erythema at the application site or at a distant site. Discontinue EUCRISA immediately and initiate appropriate therapy if signs and symptoms of hypersensitivity occur.

**Adverse Reactions**

The most common adverse reaction occurring in ≥1% of subjects in clinical trials was application site pain, such as burning or stinging.

**STUDY DESIGN AND RESULTS**

Two multicenter, randomized, double-blind, vehicle-controlled trials (Trial 1 and Trial 2) treating 1522 patients (1016 EUCRISA; 506 vehicle) with mild-to-moderate atopic dermatitis. The primary efficacy endpoint was success in Investigator’s Static Global Assessment (ISGA) at Day 29. Success in ISGA, a stringent metric, is defined as Clear (0) or Almost Clear (1) AND at least a 2-grade improvement from baseline. In the pooled results from the 2 pivotal trials, success in ISGA at Day 29 was 32.1% for EUCRISA and 21.8% for vehicle. The most common adverse reaction occurring in ≥1% of subjects in clinical trials (1012 EUCRISA vs 499 vehicle) was application site pain, such as burning or stinging.

**Learn more at** www.EucrisaHCP.com

EUCRISA® (crisaborole) ointment, 2%
Brief Summary of Prescribing Information

EUCRISA is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
Apply a thin layer of EUCRISA twice daily to affected areas. EUCRISA is for topical use only and not for ophthalmic, oral, or intravaginal use.

DOSAGE FORMS AND STRENGTHS
Ointment: 20 mg of crisaborole per gram (2%) of vehicle to off-white ointment.

CONTRAINDICATIONS
EUCRISA is contraindicated in patients with known hypersensitivity to crisaborole or any component of the formulation. [see Warnings and Precautions] WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Hypersensitivity reactions, including skin reactions, have occurred in patients treated with EUCRISA. Hypersensitivity should be suspected in the event of severe pruritus, swelling and erythema at the application site or at a distant site. If signs and symptoms of hypersensitivity occur, discontinue EUCRISA immediately and initiate appropriate therapy.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In two double-blind, vehicle-controlled clinical trials (Trial 1 and Trial 2), 1012 subjects 2 to 79 years of age with mild to moderate atopic dermatitis were treated with EUCRISA twice daily for 4 weeks. The adverse reaction reported by ≥1% of EUCRISA-treated subjects is listed in Table 1. Table 1: Adverse Reaction Occurring in ≥1% of Subjects in Atopic Dermatitis Trials through Week 4

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>EUCRISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Site Paina</td>
<td>N=1012 n (%)</td>
</tr>
<tr>
<td>Vehicle</td>
<td>N=499 n (%)</td>
</tr>
<tr>
<td>Application Site Paina</td>
<td>6 (1)</td>
</tr>
</tbody>
</table>

Adverse reactions that occurred in <1% of EUCRISA-treated subjects included: application site burning, application site pain, application site sensitization, and pruritus.

Lactation
EUCRISA is not for use in pregnancy. Use of EUCRISA in this age group is supported by evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled 28-day trials, which included 1,131 pediatric subjects 2 years and older (see Adverse Reactions and Clinical Studies in Full Prescribing Information). The safety and effectiveness of EUCRISA in pediatric patients below the age of 2 years have not been established.

Geriatric Use
Clinical studies of EUCRISA did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility
In an oral carcinogenicity study in Sprague-Dawley rats, oral doses of 30, 100, and 300 mg/kg/day of crisaborole were administered to rats once daily. A drug-related increased incidence of benign granular cell tumors in the uterus with cervix or vagina (combined) was noted in 300 mg/kg/day crisaborole treated female rats (1 times the MRHD on an AUC comparison basis). The clinical relevance of this finding is unknown. In a dermal carcinogenicity study in CD1 mice, topical doses of 2%, 5% and 7% crisaborole ointment were administered once daily. No drug-related neoplastic findings were noted at topical doses up to 7% crisaborole ointment (2 times the MRHD on an AUC comparison basis). crisaborole revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames assay and human lymphocyte chromosomal aberration assay) and one in vivo genotoxicity test (rat micronucleus assay). No effects on fertility were observed in male or female rats that were administered oral doses up to 600 mg/kg/day crisaborole (13 times the MRHD on an AUC comparison basis) prior to and during early pregnancy.

PATIENT COUNSELING INFORMATION

Advising the patient or caregiver to read the FDA-approved patient labeling (Patient Information). Hypersensitivity Reactions: Advise patients to discontinue EUCRISA at the first medical attention if signs or symptoms of hypersensitivity occur [see Warnings and Precautions]. Rx only

Rx only This Brief Summary is based on EUCRISA Prescribing Information, issued October 2017.

Download the new AAD Meeting Mobile App

The AAD Meeting Mobile App is back in 2018... and it’s better than ever! The app’s impressive functionality is easy to navigate and includes many useful features, including the following:

Session schedule
List of sessions by day, type, category, and speaker. Bookmark sessions you like, take notes, or access session handouts.

Exhibitors
Search by name or category, or view the exhibit hall floor plan.

Events
Find details on specific events, such as Council, Committee, and Task Force meetings, Affiliate and Reunion Groups, Industry Expert Sessions, and Industry Non-CME (INC) Programs.

Audience participation
Access Audience Response System sessions and provide feedback via your mobile device.

Eposters
Access eposters and search by author, title, category, keyword, or poster number.

Download the AAD Meeting Mobile App now in the App Store or Google Play by searching for “AAD Meetings.” For more information on the app, visit www.aad.org/mobile.

For anyone using a platform other than iOS or Android, there will also be a mobile website with limited functionality. Mobile App assistance is available at the San Diego Convention Center in The Connection, Hall A.
Clinical findings do not always correlate with the histology on a biopsy. An important element in arriving at a correct diagnosis is recognizing when to give weight to clinical findings and when to rely heavily on the dermatopathology report.

**Q** How important is clinicopathologic correlation in daily dermatology practice?

Dr. Hurley: Agreement, or lack of agreement, between clinical and dermatopathological findings is a conundrum that happens to all of us in everyday practice. Sometimes biopsy results can lead you astray, and other times the clinical findings can be misleading or have an extensive differential diagnosis so a biopsy is really needed to arrive at the correct diagnosis.

**Q** Are there broad principles that can guide decision-making when clinical and pathologic findings diverge?

If your clinical suspicion is high, the first step is to pick up the phone and talk with your dermatopathologist. Often, discussing the clinical picture can help expand the pathologic differential diagnosis or aide in looking for more subtle pathology. Second, it often helps to rebiopsy or do multiple biopsies, especially when there are several morphologies present on the clinical exam. One biopsy may not be representative of the entire pathological process.

**Q** Give an example of how to balance clinical and dermatopathological findings.

Mycosis fungoides is an entity where the histopathology can be subtle, and the characteristic findings are not always present on biopsies. If your clinical suspicion is high and the biopsy shows worrisome or suggestive findings, you should go on your clinical suspicion and put less weight on the biopsy. However, when you are dealing with panniculitis, where the clinical presentation of various entities is very similar, a subcutaneous nodule biopsy can provide valuable insight by delineating the inflammatory infiltrate (neutrophils, lymphocytes, or histiocytes) and help guide your treatment and additional workup.

**‘Hot Topics’ covers popular issues, newest updates**

“Hot Topics” will cover the most exciting new trends and developments in the specialty, including their implications for society and the economy, and will review several emerging and innovative therapies. Following the session, attendees will not only be able to identify the latest learnings, but will also be able to apply the evolving evidence-based knowledge to patient care.

Kenneth J. Tomecki, MD, will direct the session, which is open admission to all eligible categories. Attendees can receive a total of three CME credits for this session.

**The presentations and speakers are:**

- Ear, Nose, and Throat: The Beat Goes On
  Mark Lebwohl, MD

- Acne: What’s New?
  Hilary Baldwin, MD

- Melanoma Update 2018
  Allan Halpern, MD

- Biologics and Psoriasis: The Beat Goes On
  Zoe Draelos, MD

  Wilma Bergfield, MD

- What’s New in Cosmetic Surgery?
  Anthony Benedetto, MD

- Atopic Dermatitis: New Developments
  Lawrence Eichenfield, MD

**WHAT’S HOT?**

Don’t miss the Annual Meeting’s most sought-after session “Hot Topics,” which allows attendees to select the subjects they most want to hear about. “Hot Topics” (SO48) | Monday, 9 a.m.–12 p.m. Room 60
Help your patients take a step closer to a more normal, healthy skin color.2

REDUCE THE REDNESS

For persistent facial erythema associated with rosacea in adults

First and only
The first and only \(\alpha_{1}A\)-adrenoceptor agonist approved for the topical treatment of persistent facial erythema associated with rosacea in adults.1

Lasting results
Significantly improved erythema through 12 hours on day 29. Results were seen in 12% to 18% of RHOFADE™ cream subjects vs 5% to 9% of vehicle subjects. Individual results may vary.

Proven tolerability
Adverse reactions occurring at an incidence of \(\geq 1\%\) were application-site dermatitis, worsening inflammatory lesions of rosacea, application-site pruritus, application-site erythema, and application-site pain.1

Register for samples and learn more at rhofadehcp.com

INDICATION
RHOFADE™ (oxymetazoline HCl) cream 1% is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

IMPORTANT SAFETY INFORMATION
WARNINGs AND PRECAUTIONS

Potential Impacts on Cardiovascular Disease
Alpha-adrenergic agonists may impact blood pressure. RHOFADE™ cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and/or or uncontrolled hypertension/hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

Potentiation of Vascular Insufficiency
RHOFADE™ cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud’s phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren’s syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

Risk of Angle Closure Glaucoma
RHOFADE™ cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

ADVERSE REACTIONS
The most common adverse reactions for RHOFADE™ cream were: application-site dermatitis 2%, worsening inflammatory lesions of rosacea 1%, application-site pruritus 1%, application-site erythema 1%, and application-site pain 1%.

Please see brief summary of full Prescribing Information for RHOFADE™ cream on the following page.

RHOFADE® (oxymetazoline HCl) cream 1%

BRIEF SUMMARY—PLEASE SEE THE RHOFADE® CREAM PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

INDICATIONS AND USAGE
RHOFADE® cream is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

DOSAGE AND ADMINISTRATION
For topical use only. Not for oral, ophthalmic, or intravaginal use.

Prime the RHOFADE® cream pump before using for the first time. To do so, with the pump in the upright position, repeatedly depress the actuator until cream is dispensed and then pump three times. Discard the cream from priming actuations. It is only necessary to prime the pump before the first dose.

RHOFADE® cream tubes do not require priming.

Apply a pea-sized amount of RHOFADE® cream, once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. Wash hands immediately after applying RHOFADE® cream.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Potential Impacts on Cardiovascular Disease
Alpha-adrenergic agonists may impact blood pressure. RHOFADE® cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

Potentiation of Vascular Insufficiency
RHOFADE® cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud’s phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren’s syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

Risk of Angle Closure Glaucoma
RHOFADE® cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

ADVERSE REACTIONS
Clinical Studies Experience
Because clinical trials are conducted under varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 489 subjects with persistent facial erythema associated with rosacea were treated with RHOFADE® cream once daily for 4 weeks in 3 controlled clinical trials. An additional 440 subjects with persistent facial erythema associated with rosacea were also treated with RHOFADE® cream once daily for up to one year in a long-term (open-label) clinical trial. Adverse reactions that occurred in ≥1% of subjects treated with RHOFADE® cream through 4 weeks of treatment are presented in the table below:

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Pool of Controlled Clinical Trials</th>
<th>RHOFADE® Cream (N = 489)</th>
<th>Vehicle Cream (N = 486)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application-site dermatis</td>
<td>9 (2%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Worsening inflammatory lesions of rosacea</td>
<td>7 (1%)</td>
<td>1 (&lt; 1%)</td>
<td></td>
</tr>
<tr>
<td>Application-site pruritus</td>
<td>5 (1%)</td>
<td>4 (1%)</td>
<td></td>
</tr>
<tr>
<td>Application-site erythema</td>
<td>5 (1%)</td>
<td>2 (&lt; 1%)</td>
<td></td>
</tr>
<tr>
<td>Application-site pain</td>
<td>4 (1%)</td>
<td>1 (&lt; 1%)</td>
<td></td>
</tr>
</tbody>
</table>

In the long-term (open-label) clinical trial, the rates of adverse reactions over a one-year treatment period were as follows: worsening inflammatory lesions of rosacea (5%), application-site dermatitis (3%), application-site pruritus (2%), application-site pain (2%), and application-site erythema (2%). Subjects with persistent erythema along with inflammatory lesions were allowed to use additional therapy for the inflammatory lesions of rosacea.

DRUG INTERACTIONS
Anti-hypertensives/Cardiac Glycosides
Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives and/or cardiac glycosides is advised.

Caution should also be exercised in patients receiving alpha, adrenergic receptor antagonists such as in the treatment of cardiovascular disease, benign prostatic hypertrophy, or Raynaud’s disease.

Monoamine Oxidase Inhibitors
Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
There are no available data on RHOFADE® cream use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. A literature article describing intranasal decongestant use in pregnant women identified a potential association between second-trimester exposure to oxymetazoline (with no decongestant exposure in the first trimester) and renal collecting system anomalies. In animal reproduction studies, there were no adverse developmental effects observed after oral administration of oxymetazoline hydrochloride in pregnant rats and rabbits at systemic exposures up to 9 times and 73 times, respectively, the exposure associated with the maximum recommended human dose (MRHD). The estimated background risks of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Clinical Considerations
Fetal/Neonatal Adverse Reactions
Following repeated use of oxymetazoline hydrochloride solution nasal spray for the treatment of nasal congestion at a dose 5 times higher than recommended, one case of fetal distress was reported in a 41-week pregnant patient. The fetal distress resolved hours later, prior to the delivery of the healthy infant. The anticipated exposures for the case are 8- to 18-fold higher than plasma exposures after topical administration of RHOFADE® cream.

Lactation
No clinical data are available to assess the effects of oxymetazoline on the quantity or rate of breast milk production, or to establish the level of oxymetazoline present in human breast milk post-dose. Oxymetazoline was detected in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for RHOFADE® cream and any potential adverse effects on the breastfed child from RHOFADE® cream or from the underlying maternal condition.

Pediatric Use
Safety and effectiveness of RHOFADE® cream have not been established in pediatric patients below the age of 18 years.

Geriatric Use
One hundred and ninety-three subjects aged 65 years and older received treatment with RHOFADE® cream (n = 135) or vehicle (n = 58) in clinical trials. No overall differences in safety or effectiveness were observed between subjects ≥ 65 years of age and younger subjects, based on available data. Clinical studies of RHOFADE® cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE
RHOFADE® cream is not for oral use. If oral ingestion occurs, seek medical advice. Monitor patient closely and administer appropriate supportive measures as necessary. Accidental ingestion of topical solutions (nasal sprays) containing imidazoline derivatives (eg, oxymetazoline) in children has resulted in serious adverse events requiring hospitalization, including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma. Keep RHOFADE® cream out of reach of children.

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Made in the U.S.A.
7312410910
RHO102273 07/17 172120
AAD selects 2017 Gold Medal recipient

Honorary member receives distinguished award for extraordinary contributions

The American Academy of Dermatology (AAD) has selected Stephen A. Katz, MD, PhD, of Bethesda, Maryland, as the 2017 Gold Medal Recipient. Dr. Katz is an internationally respected physician, scientist, and administrative leader, as well as a pioneer in immunodermatology.

In his 40-year tenure as a senior investigator and then chief of NCI Dermatology Branch, Dr. Katz trained and mentored numerous national and international academic dermatology leaders, many of whom have gone on to attain high-ranking positions at institutions around the world. Since 1995, Dr. Katz has achieved great success as director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). He has been recognized by the Distinguished Executive Presidential Rank Award, the highest honor that can be bestowed upon a civil servant, for his contribution to the National Institutes of Health (NIH).

The Gold Medal is the AAD’s highest award, and is presented on a very selective basis to acknowledge outstanding and exceptional service in the field of dermatology. Gold Medal Recipients are selected by the president of the Academy and automatically become honorary members.

“I have been a member of the AAD for 47 years, during which time I have been privileged to participate in many AAD programs and initiatives,” Dr. Katz said. “As well, in my capacity as director of [NIAMS], I have had the good fortune of working together with many AAD leaders and members to help inform our legislative and executive branches of government about the impact of skin disease, the role of dermatologists, and the importance of supporting research in skin biology and skin diseases.

“I am tremendously honored to receive the Gold Medal from the AAD,” he said. “I accept the award as an acknowledgment of my lifetime commitment and contributions to dermatology, medicine, and science at a national and international level.”

Visit booth #1861 or ESKATAHCP.com to learn more about availability, application, and more.

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**Session 1**

Saturday, February 17, 2018  
1:30 PM – 2:15 PM Program  
Industry Expert Theater  
San Diego Convention Center • San Diego, CA  
Please arrive at 1:15 PM to register.  
*Lunch will be provided.*

Presented by:

Jeffrey Sobell, MD

**Session 2**

Sunday, February 18, 2018  
11:00 AM – 11:45 AM Program  
Industry Expert Theater  
San Diego Convention Center • San Diego, CA  
Please arrive at 10:45 AM to register.  
*Lunch will be provided.*

Presented by:

Jerry Bagel, MD

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VISIT BOOTH 3739
Advancing flaps for improved facial reconstruction

Flaps are key elements in facial reconstruction. Familiar flap techniques are evolving and new techniques are being introduced. These practices contribute to reconstructions that would have been considered difficult to impossible in the recent past. This topic was front and center at Friday’s forum “Techniques for Flap Success” (F022).

“Even the most familiar and well-established reconstructive techniques, such as island pedicle flaps, are evolving,” said co-session director Anna A. Bar, MD. “Most dermatologists are familiar with island pedicle flaps that move straight over, but we can now use island pedicle flaps that swing, that turn, that are larger than might be expected, and are used for different areas of the face than they were not so many years ago.”

There are new techniques for undermining and anchoring flaps, new developments in free margins, and approaches to avoid or minimize distortion. Advances in flap design and suturing have improved aesthetic outcomes and reduced the visible effects of scarring.

Continuing research has also led to the design of entirely new types of flaps. Many facial reconstructive surgeons are familiar with bilobe flaps, typically used for nasal reconstruction. Defects that are too large for bilobe reconstruction or in the wrong anatomical position can now be reconstructed using trilobe flaps. Interpolated and paramedian flap techniques have also been improved, as have periocular and ear reconstruction techniques.

“An even newer technique is tunneled and transposed flaps, which allows the surgeon to tunnel a flap under the skin and transpose it to the location of the defect,” said Dr. Bar, assistant professor of dermatology at Oregon Health & Science University. “Because the flap goes beneath the skin to the new location, it does not need to be unhooked from the original blood supply. That makes for a simpler procedure with improved results.”

Advice to improve patient care

Studies show that patients recall less than half the information given by their physicians. Use of video in medicine increases patient comprehension and satisfaction and decreases anxiety. We developed two informational videos on Mohs surgery: traditional and narrative.

The focus of the traditional video is purely didactic. The narrative video includes patient testimonials, patient-physician interaction, and animations. Our Mohs surgery patients all reported that the videos were helpful for understanding Mohs surgery, with the majority (75%) recommending the narrative over the traditional format (25%). Our study shows that technology is useful for patient satisfaction, and ultimately a balance is needed between offering a comforting narrative while setting realistic expectations about the Mohs procedure and associated risks in a succinct manner.

“Dermatologic Surgery Pearls: Optimizing Safety, Satisfaction, Efficiency” (S008)

Familiar and new types of flap techniques include:
- Periocular reconstruction
- Interpolated flaps
- Island pedicle flaps
- Ear reconstruction
- Bilobe and trilobe flaps
- Advancement and rotation flaps
- Tunneled and transposed flaps

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Instant Annual Meeting access — anytime, anywhere

Get more out of the 2018 AAD Annual Meeting experience with On-Demand Recordings. You can view the most popular sessions, catch a session you missed, or revisit one that piqued your interest.

On-Demand Recordings provide an added educational opportunity for meeting attendees as well as AAD members who weren’t able to join the conference. All recordings will be available in the Online Learning Center at the AAD website approximately four weeks after the Annual Meeting.

To purchase the offering online, visit our AAD Resource Center in Hall A. To purchase the offering onsite, or to access a complete listing of session recordings, visit www.aad.org/meetings/on-demand-recordings.
Stay connected

**TODAY’S TOP TWEETS #AAD18 @AADmember**

Another lovely day at the #AAD18, looking forward to learning some dermoscopy today @AADmember

Dr Heffernan discusses TNF blockers use in sarcoidosis—can work with tattoo sarcoidosis too! #aad18 @AADmember @mariecleger

It was a PACKED room last night at #AAD18. At least 200 #derms heard the call to recognize and treat #Hyperhidrosis! Big thanks to @Dermiralc for sponsoring the spotlight on Hyperhidrosis. #WeKnowSweat #InternationalHyperhidrosisSociety @AADmember #SanDiego

At the American Academy of Dermatology Annual Meeting this weekend where I will be presenting on ‘rejuvenating faces,’ ‘radiofrequency for skin smoothing, tightening and lifting’ and ‘safe & effective botox & filler injections. @AADskin @AADmember #AAD

Vitiligo lecture series at the @AADmember AAD conference is standing room only! This is wonderful @HarrisVitiligo @DrPearlGrimes @SeemaRDesaiMD #vitiligo #dermatology @DrCandriceHeath

Live tweeting the #vitiligo symposium at the #AAD! Full house, very exciting.

What have you done to cope with physician burnout?

“I’m trying to control more of my agenda. I started yoga. I started meditation. I try to take more control of my life and not leave it in the hands of others.”

Fernanda Kihara, MD
Sao Paulo, Brazil

“I work in clinical trials. Everybody wants things now. So it’s hard to bounce so many balls. I have aromatherapy. I put on some calming music and lavender oils.”

Ximena Graber, MD
Hialeah, Fla.

“The pressures of seeing patients, dealing with administrative-type things, and EMR are the things that stress me out the most. I just switched jobs to one where I have an extra day off, so I’m spending more time with my kids. That has helped.”

Kevin Yarbrough, MD
Clackamas, Ore.

Join the #AAD18photo Instagram Challenge
Today’s challenge: Snap a photo of you and some friends spelling out the letters “AAD” in a fun and creative way.

CONNECT FOR TODAY’S TOP POSTS
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Visit Booth 2125
Quick takes on patient management

Managing patients in the real world is seldom simple. A Friday symposium, “Common, Challenging, and Controversial Short Topics in Patient Management” (S011), offered these and other pearls from five clinical leaders.

ATOPIC DERMATITIS (AD)
- Data on the effects of bathing on AD symptoms are inconclusive.
- There is no good evidence that food allergies contribute to AD.
- Dermatologists thinking of antihistamines should instead be thinking about more potent anti-inflammatory therapy.

Eric Simpson, MD, MCR
Professor of dermatology at Oregon Health and Sciences University

PEdiATric ME LANOMA
- Pediatric nevi grow and regress more frequently than adult nevi and commonly appear atypical even though they exhibit benign biologic behavior.
- Routine biopsy of childhood scalp nevi is not recommended.
- Anogenital warts may be a sign of sexual abuse in children, but are not conclusive.

Minnelly Luu, MD
Director of pediatric dermatology, Children’s Hospital Los Angeles

SKIN CANCERS
- Most melanoma is localized — 84% — but all patients should be evaluated for metastatic disease.
- Imaging is not indicated for stage 0-II melanoma unless needed to evaluate specific signs and symptoms of metastases. CT, brain MRI, and PET-CT are appropriate for stage III-IV disease.
- Recurrent nonmelanoma skin cancer is a chronic disease.

Adam Sutton, MD, MBA
Micrographic Surgery and Cutaneous Oncology Fellow, Scripps Clinic

AESTHETIC DERMATOLOGY
- The three botulinum toxins approved for use in the United States are similar, but not interchangeable on a unit-per-unit basis.
- Long pulse lasers for vascular lesions are less painful for patients, but recovery may take longer.
- Patients are asking for vaginal rejuvenation

Zakia Rahman, MD

PSORIASIS
- Dermatologists must be cautious when assessing long-term safety and efficacy data for biologics.
- The statistical method used to account for missing data makes a significant difference in perceived benefit. Non-responder imputation is the most conservative approach; multiple imputation is more positive. Last observation carried forward is optimistic and as-observed the most optimistic.
- IL-17 inhibitors secukinumab, ixekizumab, and brodalumab should be used cautiously in patients who have or develop inflammatory bowel disease.

April W. Armstrong, MD, MPH
Vice chair and associate professor of dermatology, Keck School of Medicine, University of Southern California

Practical points on therapeutics and diagnostics

As the care of hospitalized patients becomes further specialized, dermatologists have an increasingly important role in the management of inpatients, particularly those suffering from severe cutaneous adverse reactions, such as Stevens-Johnson syndrome/toxic epidermal necrolysis and drug-induced hypersensitivity syndrome/drug reaction with eosinophilia and systemic symptoms. Early recognition and evidence-based management of these reactions can have a profound impact for these patients, and education of our non-dermatologist colleagues may, similarly, help to reduce the morbidity and mortality associated with these conditions. The consultative dermatologist must take a pragmatic approach, with a focus on our field’s evolving understanding of pathogenesis and therapeutic approaches to these life-threatening drug reactions.

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**Attend an Industry Non-CME (INC) Program**

Don’t miss out on attending Industry Non-CME (INC) Programs being held in the evening from February 15-18, 2018, in San Diego, CA. At the sponsoring company’s discretion, these programs may be promotional or educational in nature.

Programs are held conveniently at the Hilton Bayfront and/or Manchester Grand Hyatt, and cover a range of topics.

For the latest information on specific INC program titles, times, locations, and registration go to aad.org/incprograms.
ELEVATE YOUR SKINCARE WITH THE POWER OF SCIENCE

ZO'SKIN HEALTH by ZEIN OBAGI MD

BOOTH 4839
What’s that birthmark?

Birthmarks and skin disorders in newborns and young infants are common. Most are harmless, while others may be associated with significant extra-cutaneous disease. The decision of whether or not to take a family through the time, expense, and worry of assessing a birthmark often rests with dermatologists.

Using a checklist approach to evaluate birthmarks can either offer a family reassurance that the condition is benign or support the need to move forward with additional testing and treatment.

Ilona J. Frieden, MD, of the University of California San Francisco, said such an approach serves as an important guide in evaluating common vascular birthmarks, evaluating key neonatal skin diseases, and identifying whether ancillary testing is needed for pigmented birthmarks, including nevi and disorders of hypo and hyperpigmentation.

“Many times, we have a good idea of what causes a birthmark. But, is an extensive evaluation right for all patients? And who is going to pay for it?” Dr. Frieden said. “In the case of genetic testing, it’s not usually covered by insurance just because we’re curious.”

Dr. Frieden and her colleagues, Barrett J. Zlotoff, MD, associate professor at the University of Virginia, and Renee M. Howard, MD, director of dermatology at Benioff Children’s Hospital in Oakland, California, led Friday’s session, “Is it Only Skin Deep? A Checklist Approach to Diagnosing and Managing Birthmarks and Neonatal Skin Diseases” (Fog4).

The session reviewed a wide array of birthmarks and neonatal skin disorders, including the most common:
- Segmental infantile hemangiomas
- Congenital hemangiomas
- Portwine stains and Sturge-Weber risk
- Vascular stains and overgrowth
- Mosaic hamartomas
- Patterned pigmentation

Assessing, testing, and treating birthmarks is different for each type. This session guided attendees in making a specific diagnosis, evaluating the potential for extra-cutaneous conditions that could be associated with that diagnosis, and creating a checklist for each type to ensure appropriate disease-specific evaluation and care.

In every case, Dr. Frieden emphasized the importance of the condition, developing a plan for what to do and when to do it, and determining the risk for extra-cutaneous conditions.
Over 15 million Americans are living with hyperhidrosis?¹

**Did you know:**

**Primary hyperhidrosis** is an idiopathic condition, marked by excessive sweating regardless of temperature, exercise or situation.¹,²

Hyperhidrosis is shown to have the highest prevalence in younger sufferers.*¹

¹ Approximately 50% of those with hyperhidrosis never consult an HCP¹

- 60% do not know it is a medical condition
- 47% do not believe there are treatment options available

³ Approximately 70% say it frequently interferes with their daily activities.¹ The impact on quality of life has been equated to psoriasis and dermatitis.³

⁴ Approximately 86% experience moderate to severe emotional impact such as feeling unhappy and reduced confidence.⁴

Could there be more behind your patients’ excessive sweating?

**Join the conversation.**

Dermira Booth 4947 at the AAD Annual Meeting

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