



DermWorld

meeting news



See exhibit hall floor plan and exhibitor listing.
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Saturday • March 18, 2023

A Publication of the American Academy of Dermatology | Association

Late-Breaking in New Orleans

S025 – Late-Breaking Research: Session 1
Saturday, March 18
9 a.m.–12 p.m.

Location: New Orleans Theater B

S042 – Late-Breaking Research: Session 2
Saturday, March 18
1–4 p.m.

Location: New Orleans Theater B

Finish strong

Don't forget two, important, back-to-back, high-yield symposiums on Tuesday.

S059 – What's New in Dermatology
Tuesday, March 21
8–10 a.m.

Location: New Orleans Theater B

Led by Mark Lebwohl, MD, FAAD, this session offers attendees the chance to discover the latest developments in dermatology over the last 15 months.

S060 – Therapeutic and Diagnostic Pearls
Tuesday, March 21
10:15 a.m.–12:15 p.m.

Location: New Orleans Theater B

Uncover practical and valuable insights on a wide range of diseases and disorders. Panel discussion led by Robert T. Brodell, MD, FAAD.

Taking a closer look

Tips for treating skin conditions among Asian population

The advice was simple. Take extra care when treating dermatologic conditions in patients with Asian skin, said Hye Jin Chung, MD, FAAD, assistant professor of dermatology at Harvard Medical school in Boston. Dr. Chung's cautious counsel was the foundation of Friday's session, "Uo1o – Managing Unique Conditions in Asian Skin."

A large population with a broad range of conditions

In directing the session, Dr. Chung explained the importance of being attentive to the differences in Asian skin. The Asian population currently constitutes a majority of the global population, comprising nearly 60%. In the U.S., the number of people who identify as Asian is expected to grow to 41 million by the year 2050. In Canada, 25% of the population is expected to be Asian by 2036. Thus, as North America's Asian population increases, the demand



Hye Jin Chung, MD, FAAD

for experienced dermatologic care for Asian skin will increase. Specifically, according to Dr. Chung, dermatologists must become more familiar with the diagnosis and treatment of common medical conditions and cosmetic concerns.

"Asian skin is known to have higher skin irritability to topical agents. Thus, it is important to counsel patients on how to use certain medications which can cause irritation, such as topical retinoids, hydroquinone, etc.," Dr. Chung said. "For example,

it is important to start lower concentrations of topical agents and provide patient counseling on using moisturizer and gentle skin care for Asian patients."

Pigmentary and scarring considerations

Certain pigmentary and scarring disorders are common in patients with Asian skin, according to Dr. Chung. For example, melanocytes in Asian skin respond to visible light differently than in the white population. Pigmentation induced by visible light is darker and more sustained. Additionally, there is a strong genetic predisposition for keloid formation. Individuals of skin of color, including Asian ancestry, are particularly prone, she said. Dr. Chung recommended fluorouracil/steroid injections, fractional ablative laser assisted drug delivery, or pulsed dye laser when intralesional steroid

injections fail for keloids or hypertrophic scars. She also discussed a detailed technique of keloidectomy with a fillet flap.

Asian perspective

Dr. Chung also invited three experts from Asia to present at the session. Regarding pigmentary disorders, Woraphong Manuskiatti, MD, from Thailand recommends picosecond laser treatment for melasma, nevus of Ota, and Hori's nevus. Davinder Parsad, MD, IFAAD, from India reviewed recent advances in the management of pigmentary disorders (autologous non-cultured epidermal cell suspension for vitiligo, and medical and laser treatment for acquired dermal macular hyperpigmentation).

When treating patients with Asian skin, Jihee Kim, MD, PhD, from Republic of Korea encourages dermatologists to be aware of anti-aging procedures, which are popular in Asia. Dr. Kim said superficial dermal injection of neuromodulator (with or without hyaluronic acid intradermal injection), and injection of poly-D,L-lactic acid or polynucleotide are popular and effective anti-aging procedures.

Finally, Dr. Chung said, don't forget the importance of sunscreen for people with Asian skin.

"Sunscreen with visible light blocker is very important for Asian skin-typed patients with hyperpigmentation (melasma, post-inflammatory hyperpigmentation, etc.)," she said. ●



Inside

Meet the Candidates **3** Microneedling Has Global Appeal **4** Dermatology's History: Role in Treating STIs **16** Systemic Treatment for Adult Atopic Dermatitis **22**

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Who will be the future leaders of the Academy?

The Nominating Committee voted to present the following slate of candidates (listed in random order) for the 2023 Academy election of Officers, Directors, and Nominating Committee Member Representatives (West Region).

Visit the AAD Election Connection at aad.org/election to learn about this year's candidates and to interact with them on top issues via the online Ask the Candidates forum.

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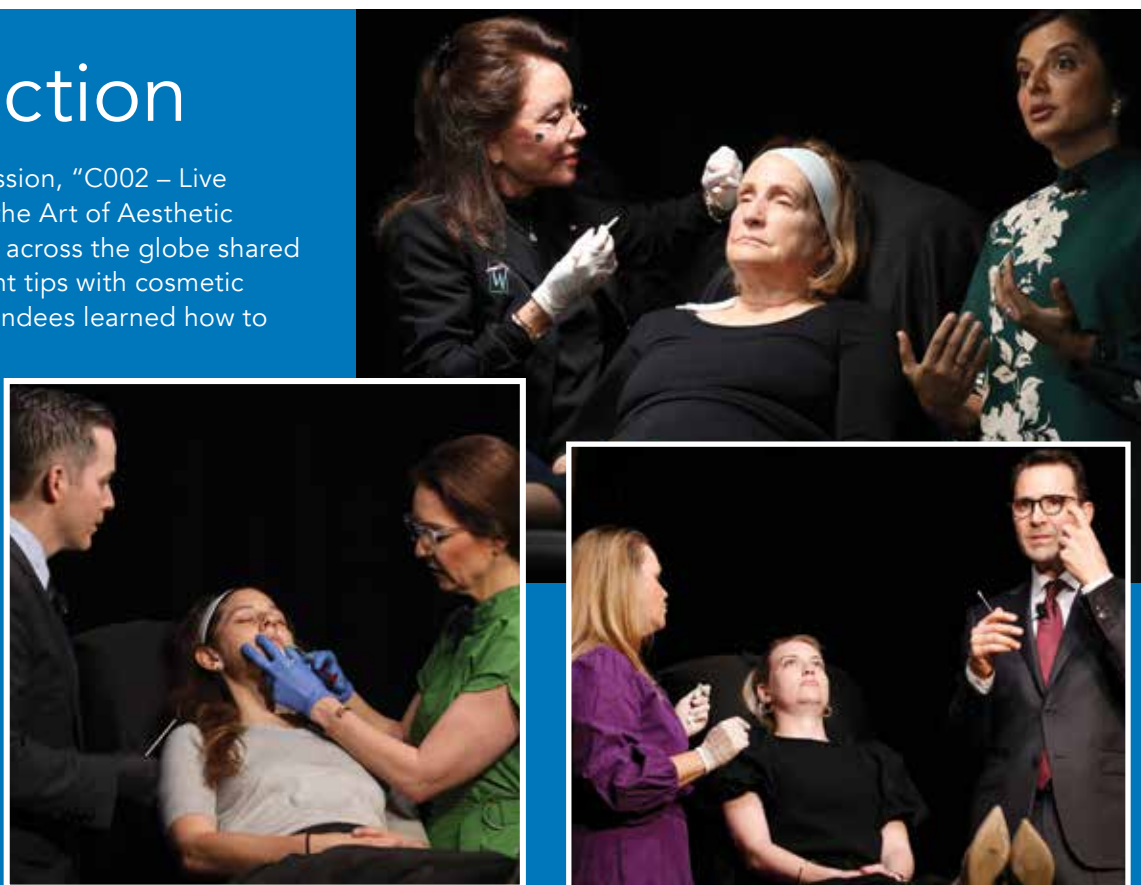
Carrie L. Davis, MD, FAAD

View/print an online ballot book at aad.org/election

Eligible voting members can vote by visiting the personalized voting link sent by email or the AAD Election Connection at aad.org/election. You can also print and fax your online secure election ballot starting March 18 to (877) 235-9052. Ballots received at the AAD office will be considered invalid.

Derm in action

During Friday's interactive session, "C002 – Live Demonstration: The State of the Art of Aesthetic Dermatology," panelists from across the globe shared their techniques and treatment tips with cosmetic procedures. In particular, attendees learned how to assess the aging face and neck and select the most appropriate aesthetic technique, how to identify the various ambulatory cosmetic procedures and their appropriate uses, and how to recognize and identify facial and neck anatomy as it relates to the use of elective procedures. Examples showcased many FDA-approved fillers, neuromodulators, deoxycholic acid, chemical peels, and microneedling.



TODAY'S HIGHLIGHTS

U041 – Developing the Next Generation of Targeted Treatments for Inflammatory Skin Diseases

7:30–8:30 a.m.

Location: Room 339

S025 – Late-breaking Research: Session 1

9 a.m.–12 p.m.

Location: New Orleans Theater B

S026 – Nail Symposium

9 a.m.–12 p.m.

Location: Room 266

S029 – Residents and Fellows Symposium

9 a.m.–12 p.m.

Location: Room 291

S030 – Boards Blitz

9 a.m.–12 p.m.

Location: New Orleans Theater C

S032 - Diversity, Equity, and Inclusion

9 a.m.–12 p.m.

Location: Room 355

S027 – Gross and Microscopic Symposium

9 a.m.–5 p.m.

Location: Room 270

DataDerm™ Drop-In Hours

10–11 a.m.

Location: AAD Resource Center, Booth 4039

Your Dermatologist Knows/ Meet the Correspondents

1–2 p.m.

Location: AAD Resource Center, Booth 4039

F063 – Self Care in Healthcare: Beyond Burnout to Finding Fulfillment

1–3 p.m.

Location: Room 276

S041 – Up-to-Date Treatment of Hair, Scalp, and Nail Disorders

1–4 p.m.

Location: Room 271

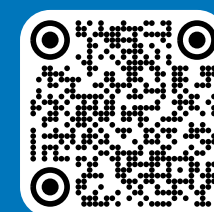
S042 – Late-Breaking Research: Session 2

1–4 p.m.

Location: New Orleans Theater B

PHOTO GALLERY

Scan the QR code below to view pics from the Annual Meeting



Microneedling has global appeal

Technique effective in all skin types.

Across the globe, microneedling has become an increasingly popular dermatologic treatment. Effective for use across all skin types and tones, it's a relatively easy treatment to integrate into a clinical practice across geographical regions.



Monica K. Li, MD, FRCPC, FAAD, clinical dermatology instructor at the University of British Columbia in Vancouver



At Friday's new session, "UO13 – Advances in Microneedling Techniques Around the World," experts discussed the benefits of the technique as well as the physician skills necessary to provide patients a safe and effective way to manage various common dermatoses, including scars of various etiologies, striae distensae, androgenetic alopecia, and rhytides.

A technique for each nuance

"Microneedling technique may vary due to specific considerations when treating different skin tones and nuances in presentation of the same medical and cosmetic applications," said session director Monica K. Li, MD, FRCPC, FAAD, a clinical dermatology instructor at the University of British Columbia in Vancouver. "When delivered as a series of treatment sessions with optimal clinical endpoints, microneedling can be an effective, real-world practice option for both facial and body sites."

Dr. Li engaged the expertise of dermatologists from Brazil, Spain, and Thailand to share their perspectives on microneedling around the globe as well as its use in facilitating transdermal drug delivery. The panel also evaluated evidence-based practices comparing microneedling, radiofrequency microneedling, and microcoring. According to Dr. Li, microneedling is considered generally safe for all skin tones, delivering negligible thermal energy. However, recognizing the appropriate aesthetic and medical conditions is key to optimize outcomes. For example, she said, needle depths should be adjusted to the specific skin location and skin thickness. Consider, too, that deeper needle penetration may be necessary for thick sebaceous skin compared to thin periocular skin.

Pearls on the healing process

"Combining microneedling with the use of topical antioxidants can enhance the regenerative process in the wound healing process resulting from the treatment, specifically with topical vitamin A and C," she said. "However, products not approved for intradermal use during microneedling may cause allergic contact dermatitis or granuloma formation."

Additionally, Dr. Li said patients should be educated about the procedure and be able to commit to the necessary post-procedure care to minimize adverse effects, including the risk of infection. Depending on the skin concern, the benefits of microneedling can be leveraged as part of combination therapies to improve different characteristics seen with scars and striae such as color and texture, she said.

Tuning in to microchannels

Microneedling is also effective in facilitating transdermal drug delivery, Dr. Li said. Specifically, microneedling induces the production of microchannels by way of controlled skin injury with minimal epidermal damage. These microchannels serve as conduit for enhanced penetration of medications that otherwise may not be able to reach the dermis to exert its intended effects.

From a clinical perspective, the difference between microneedling and radiofrequency microneedling is the manually delivered approach with no additional energy to induce collagen remodeling and production, she said.

"Radiofrequency microneedling delivers radiofrequency energy simultaneously as microneedles penetrate the skin, and this is thought to be able to amplify collagen and elastin production," she said. "Because of the added energy, some feel that fewer treatments may be required for radiofrequency microneedling compared to microneedling alone for treatment of the same skin concern. However, this is not conclusive from literature to date." ●

Microneedling tips



Scars and striae typically require a series of three to five monthly microneedling treatments.



Avoid microneedling on visibly tanned skin or those with recent sun exposure to prevent potential post-procedure dyspigmentation.



Do not perform microneedling over skin that shows signs of active infection or inflammation (active acne).



Apply a cross-hatch technique when delivering microneedling passes to prevent skip areas.



Pinpoint bleeding is a useful clinical treatment endpoint.



Microneedling can be performed on discrete cosmetic units without producing lines of demarcation, unlike fully ablative laser resurfacing.



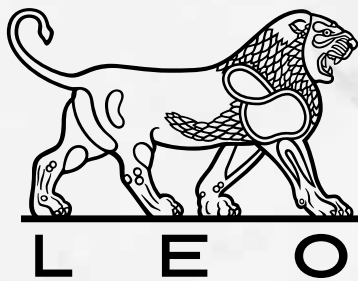
Take extra caution in the application of topical products or medications that are not approved for intradermal use during microneedling, as it may lead to possible allergic contact dermatitis or granuloma formation.

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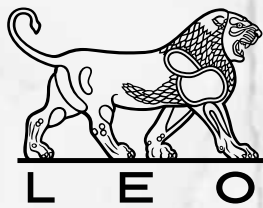
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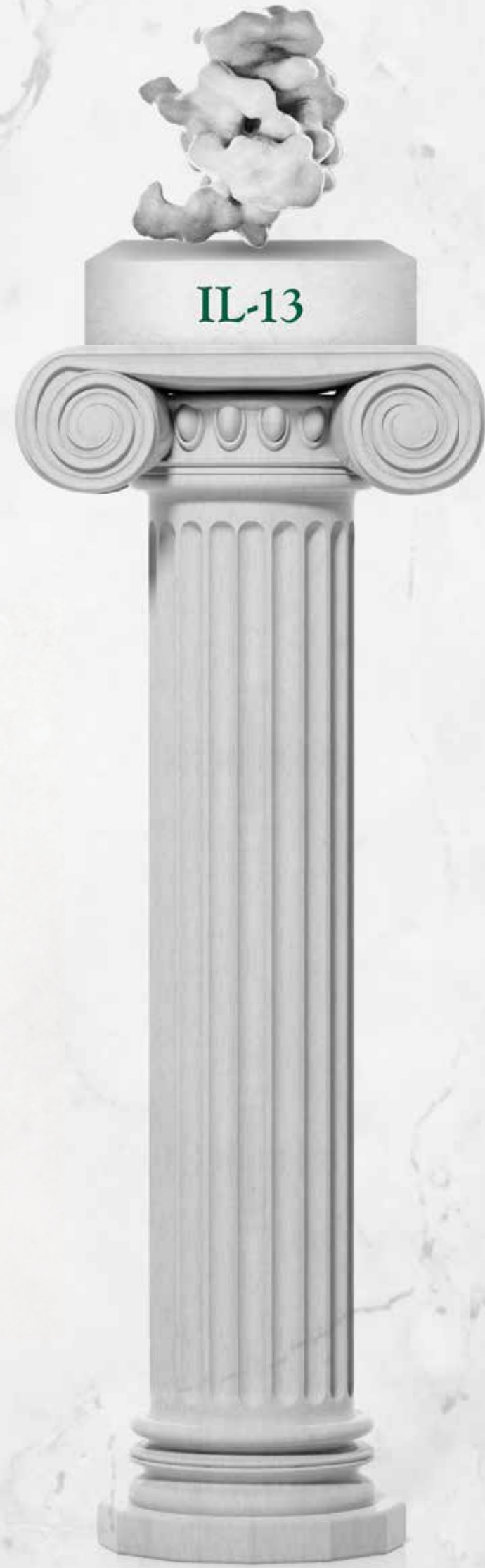
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Don't miss Poster Presentations

The Poster Presentation Centers 1 and 2 featuring live presentations and e-Posters are located just inside the Exhibit Hall.

Hours:

Saturday
8:30 a.m.–5 p.m.

Sunday
1–3 p.m.



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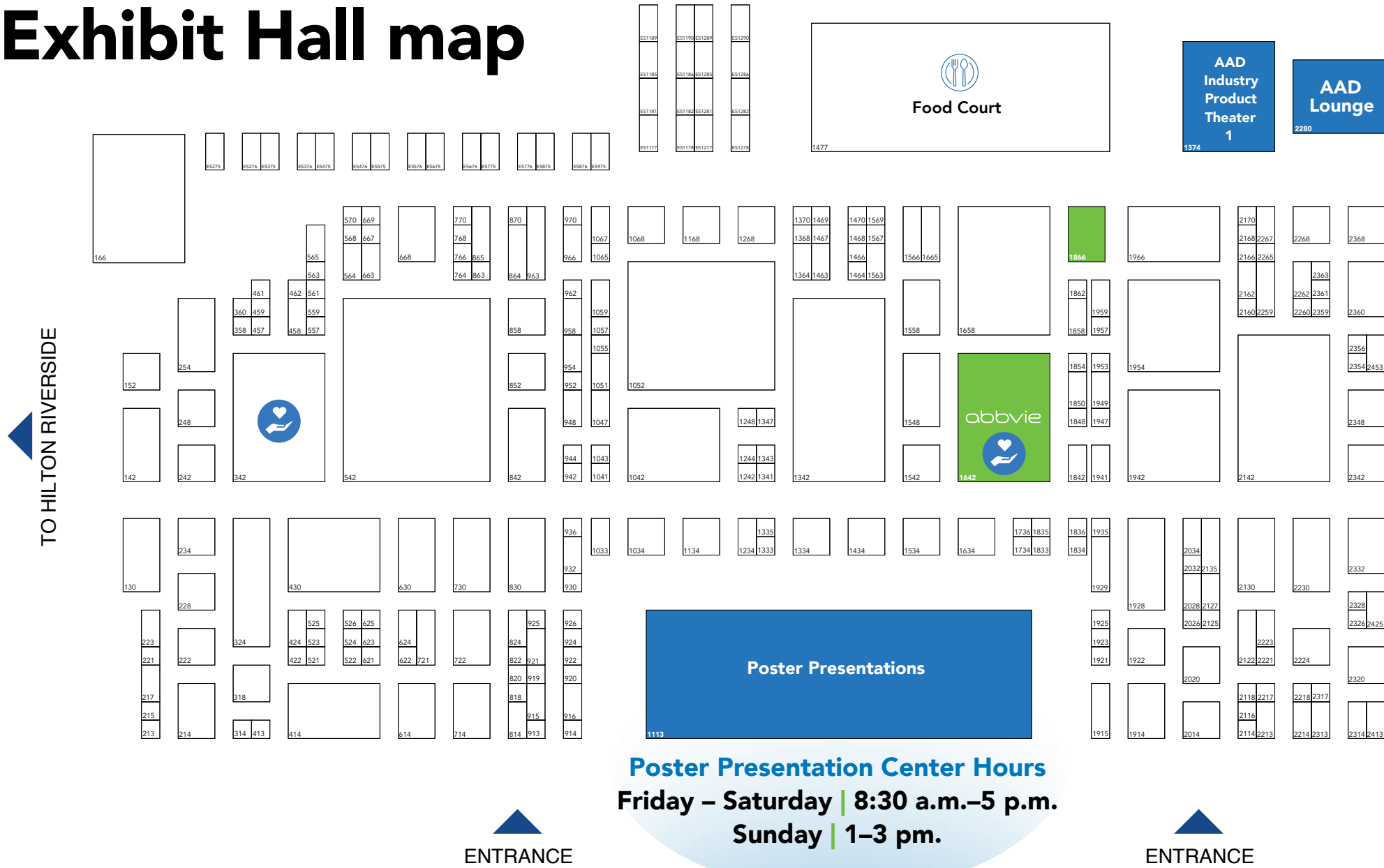
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Exhibit Hall map



Poster Presentation Center Hours
Friday – Saturday | 8:30 a.m.–5 p.m.
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Exhibitor Listing

Data current as of February 21, 2023. Please use the AAD Meeting App aad.org/mobile for the most up-to-date exhibitor list.

3Gen, Inc./DermLite	1928	APDerm	624	Clinical Skin LLC	3850	DermPath Diagnostics	614
5CC (5-Continent-Congress)	1248	Aqua Dermatology	1364	CLN Skin Care (TopMD Skin Care)	2326	DermTech	2839
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AAD Member Buying Program	4543	Baitella AG	522	Connect Biopharm	4221	eClinicalWorks	1059
AAD Preferred Provider	4549, 4551	Bank of America Practice Solutions	930	Coolibar, Sun Protection You Wear	4231	EllaOla Brands Inc.	766
AAD Registration	2757	Beiersdorf, Inc.	3139	Coous Global Co., Ltd.	2314	Ellis Instruments	2214
AAD Resource Center	4039	Beijing Sincoheren		Coronado Aesthetics LLC	3457	Elsevier	2135
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Accurate Manufacturing, Inc.	2832	Beutner Laboratories	1467	CuraScript SD	4227	Epionce	3619
AccuTec Inc.	2114	Biodermis	3632	Cutera	730	Epiphany Dermatology	865
Acuderm	2532	Biofrontera, Inc.	2224	Cyspera by Scientis US	459	EunSung Global Corp	722
AD Surgical	924	BioLab Sciences	4314	Cytrellis Biosystems	565	EUROIMMUN US	1051
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Advanced Dermatology		Bison Medical	916	Dartmouth Health	942	Dermatology and Venereology	4054
& Cosmetic Surgery	458	Boehringer Ingelheim		DefenAge	814	Evme inc.	461
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Aeon Biotherapeutics Corp.	1468	Bristol-Myers Squibb	3147, 2267	Delasco	921	EZDerm, LLC	1034
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Allergan Aesthetics	1134, 1342	Candela	1042	DERMAGNOSTIX	3852	FineMec Co, Ltd	824
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Alma Lasers	830	Cara Therapeutics	1953	DermaSensor Inc.	2221	Forefront Dermatology	858
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AMLo Biosciences	4541	Clarius Mobile Health	3557	Dermogalenic Experts SA DE CV	564	GALDA: Gay & Lesbian Dermatology	
Anne Arundel Dermatology, P.A.	1959	CLASSYS	2320	Dermosciences Corp	570	Association Found	1244

Exhibit Hall hours

Saturday | 10 a.m.–5 p.m.

Sunday | 10 a.m.–3 p.m.

AAD Industry Product Theater 2

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2442 2642

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- Incyte Corporation 4313
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- Journal of Clinical and Aesthetic Dermatology 1341
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- Karger Publishers 1848
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- National Eczema Association 2328
- National Psoriasis Foundation 213

see EXHIBITOR LISTING page 15

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Neutrogena	3113
Newmedical Technology, Inc.	4431
Nextech	2230
NextPatient, Inc.	932
Nitra	2354
No7	2360
Nobelpharma America	3856
NoIR LaserShield	621
Novartis Pharmaceuticals Corporation	2442, 2468
Novoxel Ltd.	822
Nutrafol	1566
Obagi Medical Products	3047
Olink Proteomics, Inc.	3657
OM1	4547
Opulus Beauty Labs	4312
Ortho Dermatologics	2825
Otto Trading Inc.	2830
Overnia	2259
Padagis	4432
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PathologyWatch	521
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President's GALA

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CURRENT AT TIME OF PRODUCTION

Dermatology's history, role in treating STIs

Now, mpox joins the list.

Dermatologists are on the front lines in the ongoing battle to prevent and treat sexually transmitted infections.

“Dermatology as a specialty began from a study of syphilology because syphilis causes so many, many skin rashes,” said Kieron Leslie, MBBS, professor of dermatology at the University of California, San Francisco (UCSF) School of Medicine. “Similarly, condyloma, mpox, and many other sexually transmitted infections (STIs) are primarily diseases of the skin. When someone comes in with a lesion on the face, the hands, the trunk, they may not share that they also have genital lesions. You need to have an index of suspicion that this might be an STI.”

Thinking outside the pox

Dr. Leslie opened Friday's session, “F014 – HIV and STIs: Hot Topics” with an update on the latest skin disease to jump from animals to humans, mpox. Since the 1950s, mpox had been considered a zoonotic infection endemic to parts of Africa that can jump from animals to humans, but human-human transmission was rare. That changed in 2022 when mpox suddenly surged to pandemic status. Spread largely, but not exclusively, through sexual contact,

mpox can present as a mild rash to more painful and severe rashes and anogenital lesions.

The good news, according to Dr. Leslie, is that incidence rates in the United States have fallen significantly since the summer of 2022. The drop is likely due to a combination of aggressive vaccination, emphasis on safe sex practices, and widespread infection among the most susceptible populations.

“Dermatologists need to be aware of the morphology of mpox and other STIs because cases continue to present,” Dr. Leslie said. “Symptom control is standard of care for mild disease with analgesia for more severe forms. For severe disease, antivirals potentially active against poxvirus are appropriate.”

Jump on STOMP

The primary antiviral is tecovirimat, approved under an Emergency Use Authorization (EUA). The agent is also being evaluated in STOMP, the Study of Tecovirimat for Human Mpox.

“For patients who present with mpox, we recommend they get enrolled in STOMP,” he said. “Tecovirimat has been evaluated in phase I safety trials and is effective in monkeys, but efficacy in humans has not been evaluated. We hope STOMP will



Kieron Leslie, MBBS, professor of dermatology at the UCSF School of Medicine

answer the question. Mpox remains a long-standing infectious disease that presents in the skin. Dermatologists need to be aware of what the rashes and lesions look like and be able to refer to appropriate treatment.”

Making safe sex even safer

Practitioners need to be equally familiar with syphilis, HIV, condyloma, and other STIs and the latest prevention strategies. And while treatments are available, prevention is preferred.

Safe sex practices can make a significant difference, Dr. Leslie said. So can vaccination, which has dramatically reduced the incidence and prevalence of condyloma and other sequelae of human papilloma virus (HPV) infection.

The Advisory Committee on Immunization Practices (ACIP) recommends HPV vaccination for all individuals up to the age of 26 and up to age 45 based on individual factors. HPV



Albert Liu, MD, MPH, assistant clinical professor at the UCSF School of Medicine and director of HIV Prevention, San Francisco Department of Public Health

vaccination is not recommended for older individuals based on both the likelihood of prior HPV infection and the generally lower immune response in older individuals.

PrEP, preexposure prophylaxis, has been used to prevent HIV transmission for a decade, as has PEP (post exposure prophylaxis), according to Albert Liu, MD, MPH, assistant clinical professor at the UCSF School of Medicine and director of HIV Prevention, San Francisco Department of Public Health. The same PrEP-PEP approach has been extended to syphilis using doxycycline, a perennial treatment of choice for acute and secondary syphilis.

“Using doxy as PrEP and PEP is new for syphilis, but the strategies are well established and successful in HIV,” Dr. Liu said. “Dermatologists need to understand that there are highly effective prevention strategies for HIV and syphilis and be comfortable talking with patients about their sexual history and activity.” ●

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In DERMIS-1 and DERMIS-2, ~40% of patients achieved IGA Success and ~70% of patients achieved I-IGA Success at Week 8.¹

DERMIS-1 and DERMIS-2 were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multicenter studies that evaluated ZORYVE over 8 weeks as a once-daily, topical treatment for plaque psoriasis. Subjects (N=881) were randomized 2:1 to receive ZORYVE cream 0.3% (n=576) or vehicle (n=305) applied once daily for 8 weeks. Eligibility criteria included a diagnosis of mild, moderate, or severe plaque psoriasis and an affected BSA of 2% to 20%. Primary endpoint was IGA Success at Week 8 and key secondary endpoint was I-IGA Success at Week 8.¹

IGA Success was defined as a score of Clear (0) or Almost Clear (1) and a ≥ 2 -grade improvement from baseline. I-IGA Success was defined as a score of Clear (0) or Almost Clear (1) and ≥ 2 -grade improvement from baseline.

ZORYVE is not for ophthalmic, oral, or intravaginal use.

BSA = Body Surface Area, IGA = Investigator's Global Assessment, I-IGA = Intertriginous-IGA

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INDICATION

ZORYVE is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). The most common adverse reactions ($\geq 1\%$) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see brief summary of full Prescribing Information for ZORYVE on the following page.

References: 1. ZORYVE®. Prescribing information. Arcutis Biotherapeutics, Inc; 2022. 2. Data on File. Arcutis Biotherapeutics, Inc.



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COM-ARQ-151-2100003 v4.0 02/2023

Brief Summary of Prescribing Information for ZORYVE™ (roflumilast) cream, for topical use. See package insert for full Prescribing Information.

INDICATIONS AND USAGE

ZORYVE is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION

Apply ZORYVE to affected areas once daily and rub in completely. Wash hands after application, unless ZORYVE is for treatment of the hands.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.

CONTRAINDICATIONS

The use of ZORYVE is contraindicated in the following condition:

- Moderate to severe liver impairment (Child-Pugh B or C)

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 multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2), 881 subjects 2 years of age or older with plaque psoriasis were treated with ZORYVE or vehicle once daily for 8 weeks.

The median age was 47 years (range 6 to 88). The majority of the subjects were male (64%) and White (82%). The median body surface area (BSA) affected was 5.5% (range 2% to 20%).

The proportion of subjects who discontinued treatment due to adverse reaction was 1.0% for subjects treated with ZORYVE and 1.3% for subjects treated with vehicle. The most common adverse reactions that led to discontinuation of ZORYVE was application site urticaria (0.3%).

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ZORYVE, and for which the rate exceeded the rate for vehicle.

Table 1. Adverse Reactions Reported in ≥1% of Subjects Treated with ZORYVE for 8 Weeks

Adverse Reaction	ZORYVE (N=576) n (%)	Vehicle (N=305) n (%)
Diarrhea	18 (3.1)	0 (0.0)
Headache	14 (2.4)	3 (1.0)
Insomnia	8 (1.4)	2 (0.7)
Nausea	7 (1.2)	1 (0.3)
Application site pain	6 (1.0)	1 (0.3)
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary tract infection	6 (1.0)	2 (0.7)

In 594 subjects who continued treatment with ZORYVE for up to 64 weeks in open-label extension trials, the adverse reaction profile was similar to that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no randomized clinical trials of oral or topical roflumilast in pregnant women. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 9 and 8 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 3 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 5 and 15 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 15 times the MRHD during pregnancy and lactation periods in mice.

The background risk of major birth defects and miscarriage for the indicated population is unknown. 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

Labor and delivery

ZORYVE should not be used during labor and delivery. There are no human studies that have investigated effects of ZORYVE on preterm labor or labor at term; however, animal studies showed that oral roflumilast disrupted the labor and delivery process in mice.

Data

Animal data

In an embryo-fetal development study, pregnant rats were dosed orally during the period of organogenesis with up to 1.8 mg/kg/day roflumilast (9 times the MRHD on a mg/m² basis). No evidence of structural abnormalities or effects on survival rates were observed. Roflumilast did not affect embryo-fetal development at a maternal oral dose of 0.2 mg/kg/day (equivalent to the MRHD on a mg/m² basis).

In a fertility and embryo-fetal development study, male rats were dosed orally with up to 1.8 mg/kg/day roflumilast for 10 weeks and females for 2 weeks prior to pairing and throughout the organogenesis period. Roflumilast induced pre- and post-implantation loss at maternal oral doses greater than or equal to 0.6 mg/kg/day (3 times the MRHD on a mg/m² basis). Roflumilast did not cause fetal structural abnormalities at maternal oral doses up to 1.8 mg/kg/day (9 times the MRHD on a mg/m² basis).

In an embryo-fetal development study in rabbits, pregnant does were dosed orally with 0.8 mg/kg/day roflumilast during the period of organogenesis. Roflumilast did not cause fetal structural abnormalities at the maternal oral doses of 0.8 mg/kg/day (8 times the MRHD on a mg/m² basis).

In pre- and post-natal developmental studies in mice, dams were dosed orally with up to 12 mg/kg/day roflumilast during the period of organogenesis and lactation. Roflumilast induced stillbirth and decreased pup viability at maternal oral doses greater than 2 mg/kg/day and 6 mg/kg/day, respectively (5 and 15 times the MRHD on a mg/m² basis, respectively). Roflumilast induced delivery retardation in pregnant mice at maternal oral doses greater than 2 mg/kg/day (5 times the MRHD on a mg/m² basis). Roflumilast decreased pup rearing frequencies at a maternal oral dose of 6 mg/kg/day during pregnancy and lactation (15 times the MRHD on a mg/m² basis). Roflumilast also decreased survival and forelimb grip reflex and delayed pinna detachment in mouse pups at a maternal oral dose of 12 mg/kg/day (29 times the MRHD on a mg/m² basis).

Lactation

Risk Summary

There is no information regarding the presence of ZORYVE in human milk, the effects on the breastfed infant, or the effects on milk production.

Roflumilast and/or its metabolites are excreted into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZORYVE and any potential adverse effects on the breastfed infant from ZORYVE or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply ZORYVE directly to the nipple and areola to avoid direct infant exposure.

Data

Animal data

Roflumilast and/or its metabolite concentrations measured 8 hours after an oral dose of 1 mg/kg given to lactating rats were 0.32 and 0.02 mcg/g in the milk and pup liver, respectively.

Pediatric Use

The safety and effectiveness of ZORYVE have been established in pediatric patients ages 12 years and older for the treatment of plaque psoriasis. Use of ZORYVE in this age group is supported by data from two 8-week vehicle-controlled safety and efficacy trials which included 14 adolescent patients aged 12 to 17 years, of whom 8 received ZORYVE. Eighteen adolescent patients were treated with ZORYVE in open-label trials of 2- and 24-weeks duration. The adverse reaction profile was similar to that observed in adults.

The safety and effectiveness of ZORYVE in pediatric patients below the age of 12 years have not been established.

Geriatric Use

Of the 881 subjects with psoriasis exposed to ZORYVE or vehicle for up to 8 weeks in 2 controlled clinical trials, 106 were 65 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the geriatric and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Based on available data for roflumilast, no adjustment of dosage in geriatric patients is warranted.

Hepatic Impairment

Oral roflumilast 250 mcg once daily for 14 days was studied in subjects with hepatic impairment. The AUC and C_{max} values of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

PATIENT COUNSELING INFORMATION

Advise the patient or caregiver to read the FDA-approved patient labeling (Patient Information).

Are you up for a challenge?

Good news! The ever-popular social media challenges will be returning to the AAD Annual Meeting in New Orleans. This year, there will be two different challenges that attendees can participate in — one on Twitter and one on Instagram. Both will offer the jealousy-inducing grand prize of **free registration to the 2024 Annual Meeting in San Diego!** Attendees are encouraged to participate in both challenges, and there is no limit to the number of entries submitted on either platform.

Instagram Reel Challenge

Gone are the days of posting selfies and photo carousels — video is the new way of sharing your best content on social media. We are asking attendees to share their Annual Meeting experience by creating an Instagram Reel of their time in The Big Easy with the hashtag #AAD2023challenge. Reels can be posted any time between Friday, March 17, and Tuesday, March 21, until 11:59 PM CDT. One grand prize winner will be randomly selected from the total submissions the following week and the reel will be shared from the @AADmember Instagram account.

Twitter Pearl Challenge

Twitter is still one of the most popular platforms for dermatologists to share research and discuss specialty topics. Since there is so much to learn about at the Annual Meeting, we are asking attendees to tweet their top pearls or key learnings from their favorite AAD sessions with the hashtag #AAD2023challenge to enter. One randomly chosen winner will be selected the week after the meeting ends.

For more information, see the official rules and regulations online at aadmeetingnews.org/22724379 or direct message @AADmember on Twitter or Instagram.



Pearls from Members

Brad P. Glick, DO, MPH, FAAD

Member, AAD Board of Directors, residency program director, Larkin Palm Springs Hospital, Miami



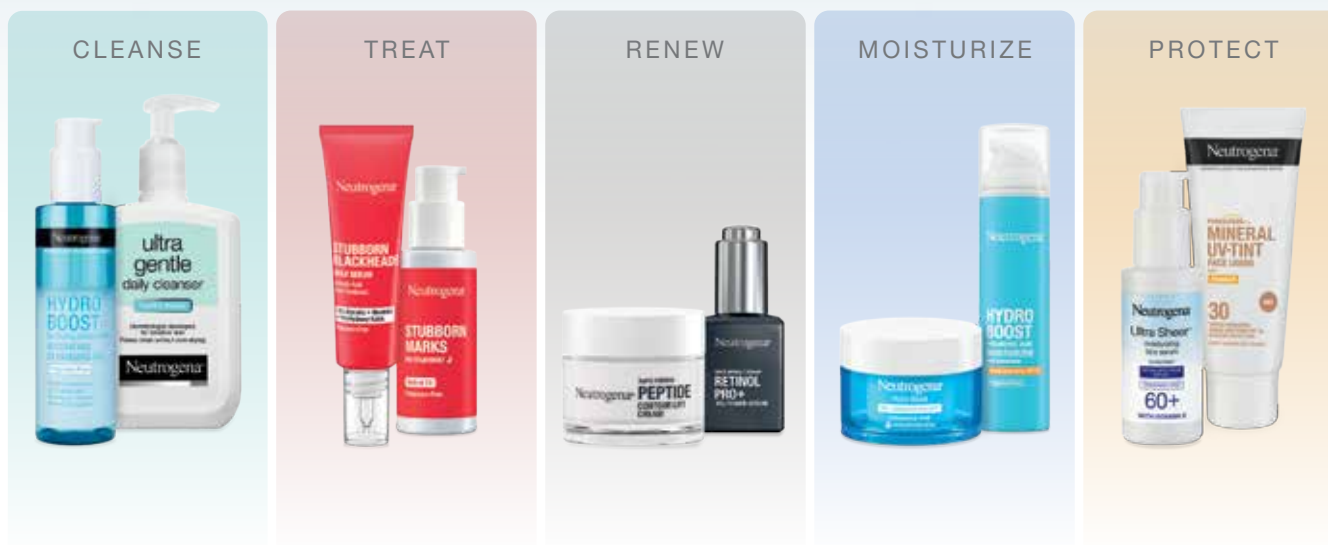
New Approvals

“Patients with severe plaque psoriasis and comorbid Crohn’s disease, who have failed multiple topical, oral systemic, and biologic therapies such as TNF factor inhibitors, should consider the use of risankizuma. It’s a highly effective interleukin 23 targeted biologic therapy that now will provide coverage for the skin, the joints, and the gut as it has been recently FDA approved for Crohn’s disease.”

Dr. Glick is among the panel of judges for today’s **S029 - Resident and Fellows Symposium** in Room 291 from 9 a.m.–12 p.m.

In a study of patients with acne, almost 40% of treatment non-adherence was due to side effects¹

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References: 1. Dikicier BS. Topical treatment of acne vulgaris: efficiency, side effects, and adherence rate. *J Int Med Res.* 2019;47(7):2987-2992. 2. Lain E, Andriessen AE. Choosing the right partner: complementing prescription acne medication with over-the-counter cleansers and moisturizers. *J Drugs Dermatol.* 2020;19(11):1069-1073. 3. Dreno B, Araviiskaia E, Kerob Delphine, et al. Nonprescription acne vulgaris treatments: their role in our treatment armamentarium—an international panel discussion. *J Cosmet Dermatol.* 2020;19:2201-2211.

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The practical side of systemic treatment for adult atopic dermatitis

Late-onset AD is a reality.

Adults get atopic dermatitis less frequently than children but are often more difficult to treat than kids. Those easy-to-miss realities leave too many adults with atopic dermatitis undiagnosed and untreated. Even adults who are diagnosed are too often undertreated and suffering needlessly when dermatologists are slow to suggest escalating to systemic treatments. These issues were addressed during Friday's session, "UO12 – Practical Considerations for Systemic Treatment of Atopic Dermatitis in Adults," led by Aaron Mark Drucker, MD, FAAD, and including presentations by Katrina Abuabara, MD, FAAD, as well as Eric Lawrence Simpson, MD, MCR, FAAD.

What's new?

New and different approaches are here. Dermatologists have long used methotrexate, cyclosporin, and azathioprine off label for atopic dermatitis, but clinical trial data are sparse, noted Dr. Drucker, a scientist at Women's College Research Institute and associate professor of medicine at the University of Toronto Institute of Health Policy, Management, and Evaluation in Canada.

"In 2017, we began to get targeted systemic treatments, starting with dupilumab; then tralokinumab was approved. Now we have Janus kinase (JAK) inhibitors approved in the U.S. and Canada. The most important considerations are always how



Aaron Mark Drucker, MD, FAAD



Katrina Abuabara, MD, FAAD; Eric Lawrence Simpson, MD, MCR, FAAD

effective it is and how safe it is, along with cost and accessibility," Dr. Drucker said.

Biologics and JAK inhibitors are both effective, Dr. Drucker said. At higher doses, JAK inhibitors are somewhat more effective than biologics, but also carry greater safety concerns.

"These agents are amazing for patients, and we've got more options that can, hopefully, improve patients' lives with more on the way," he said. "But more effective agents also make conversations with patients and decision making more complex. There are multiple factors to keep in mind, and we must make decisions with patients, not for them."

It's complicated

Dr. Abuabara, an associate professor of dermatology at the University of California, San Francisco, discussed some of the issues surrounding systemic treatment for adults. She asserted that treating adults with atopic dermatitis can be more complicated than treating children because adults have more conflicting considerations and demands on their time.

"Atopic dermatitis is quite common in adults," Dr. Abuabara

said. "The older studies that talked about most atopic dermatitis developing by age two weren't necessarily wrong, but they were limited. If you only follow people to age seven, the majority get it by age two. When you extend the window of observation, you see higher and higher proportions of people with later and later onset of disease."

Topicals are the first-line approach, but it can sometimes be difficult to convince an adult to apply cream or ointment to their skin consistently before work every day. Patients with disease on their face or hands may not be able to go to work, she said, while particularly itchy disease may impact sleep quality, which affects their quality of life.

"There are logistic factors with adults and topical treatments can be time-consuming and messy, which they won't tolerate. Phototherapy can be effective and is very safe, but it requires going in two or three times a week, which can present work or transportation challenges and sometimes results in high co-pays. And there are patients who have tried topical steroids for years without success and want something new and different."

Lingering questions

The real question is whether the patient thinks their symptoms are under adequate control with the current therapy, said Dr. Simpson, professor of dermatology at Oregon Health and Science University School of Medicine in Portland. If the answer is 'no,' the disease is still bothersome, still has an impact on quality of life. It's time to talk systemic treatment.

"Your responsibility is to care for your patient," Dr. Simpson said. "And if they're telling you that they are still suffering, despite what you think is an adequate topical or other treatment, they deserve the systemic treatment conversation."

The biggest obstacle to appropriate use of systemics is therapeutic inertia, he said. Clinicians tend to continue using the same approaches they've used in the past.

"There is a real hesitancy to escalate treatment and patients suffer because of it," Dr. Simpson said. "We need to recognize earlier the failure of topical therapy and the continued suffering that brings our patients. We need to offer treatment escalation earlier because, in general, adults with atopic dermatitis are undertreated." ●

Exam session provides extra insights into structure, career

Jumpstart your exam prep with this year's new session, **F051 – Boards & Beyond**. Board-certified dermatologists will provide residents with an understanding of the structure, format, and process of taking the American Board of Dermatology examination as well as tips on post-residency topics such as disability and life insurance, budgeting, and retirement planning.

The first hour of the session will cover board review. The second hour will focus on financial matters residents can use to prepare for a successful future after residency.

The session is for residents, young physicians, and even practicing dermatologists.

F051 – Boards And Beyond
Saturday, March 18
1–3 p.m.
Location: Rooms 255-257

AAD selects 2023 Gold Medal recipient

During the AAD/A Annual Business Meeting, Daniel Mark Siegel, MD, MS, FAAD, of New York, will be honored as the 2023 Gold Medal Recipient. Dr. Siegel is a respected physician and leader.

Dr. Siegel founded the division of dermatologic surgery at State University of New York Stony Brook and ran the division for 12 years, establishing a fellowship training program, while actively teaching medical students and dermatology residents. Dr Siegel

was named the American Academy of Dermatology's representative to the AMA practice expense advisory committee, a subcommittee of the congressionally mandated AMA/Specialty Society RVS Update committee (RUC). Dr. Siegel is currently a clinical professor of the dermatology department at the State University of New York at Downstate Medicine where he teaches residents and medical students.

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 believe my greatest contribution to the specialty is talent spotting and mentoring individuals to reach their full potential to succeed in their careers and provide service to the profession and the community." ●



Daniel Mark Siegel, MD, MS, FAAD
2023 Gold Medal Recipient



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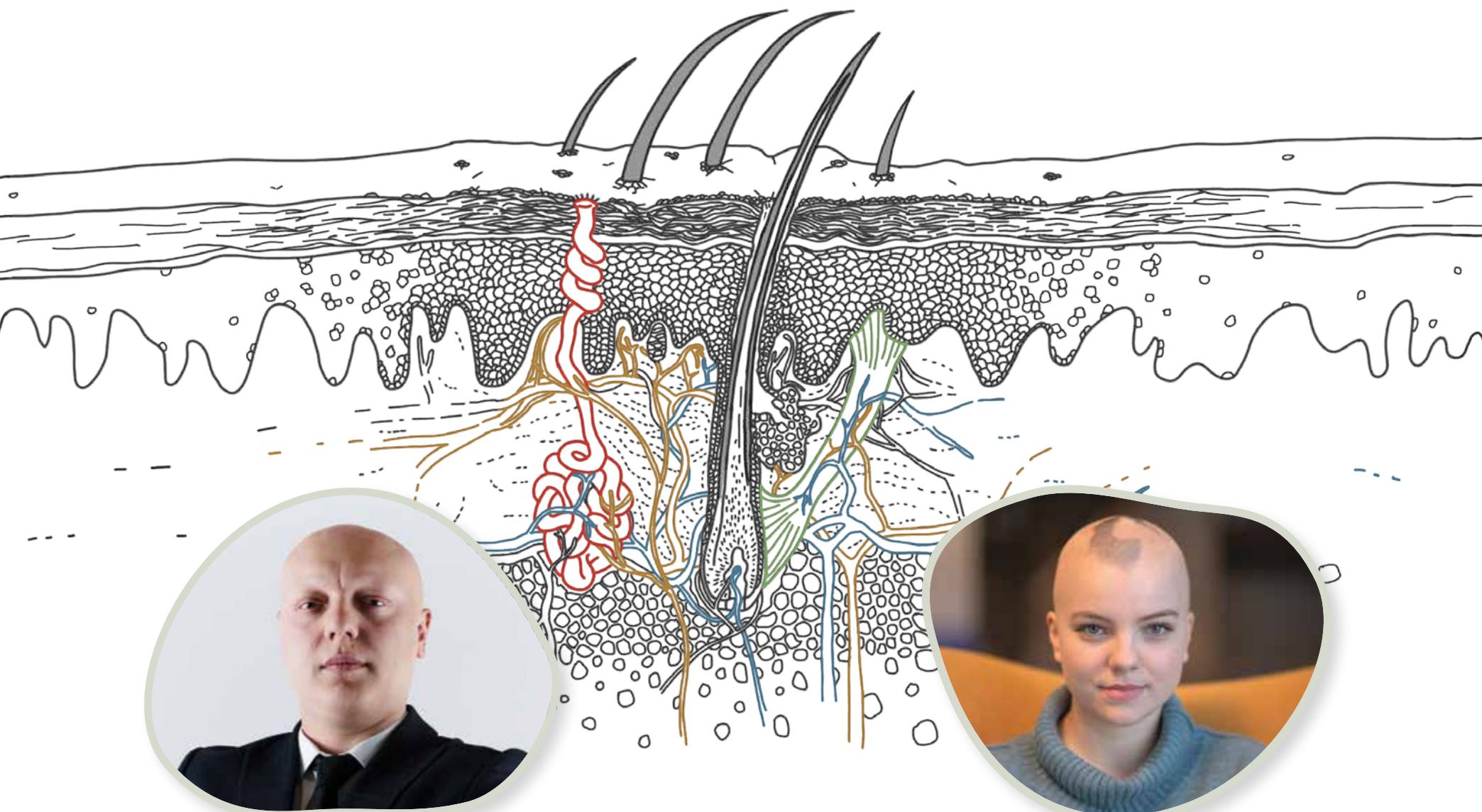
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Hair loss isn't the whole story.

- Alopecia areata (AA) is an autoimmune disease that can also have effects beyond the scalp.¹
- AA has a complex etiology and is rooted in immune system dysregulation, with many patients having a genetic predisposition.^{2,3}
- Patients often experience autoimmune and psychiatric comorbidities, lifestyle disruptions, and psychosocial distress.^{1,2,4}
- The unpredictable course of AA can make disease management difficult for HCPs and their patients.^{5,6}

To re-examine what you know about alopecia areata, visit education.lillymedical.com/advancesinaa



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