



DermWorld

meeting news



See Exhibit Hall floor plan and exhibitor listing. **PAGES 12-14**

Friday • March 8, 2024

A Publication of the American Academy of Dermatology | Association



Late-Breaking in San Diego

For 2024, the AAD is offering two Late-Breaking Research sessions on consecutive days, both led by Hensin Tsao, MD, PhD, FAAD.

Location: Room 20B

Saturday, March 9
9 a.m.-noon
S026 – Late-Breaking Research: Session 1

Sunday, March 10
1-4 p.m.
S050 – Late-Breaking Research: Session 2



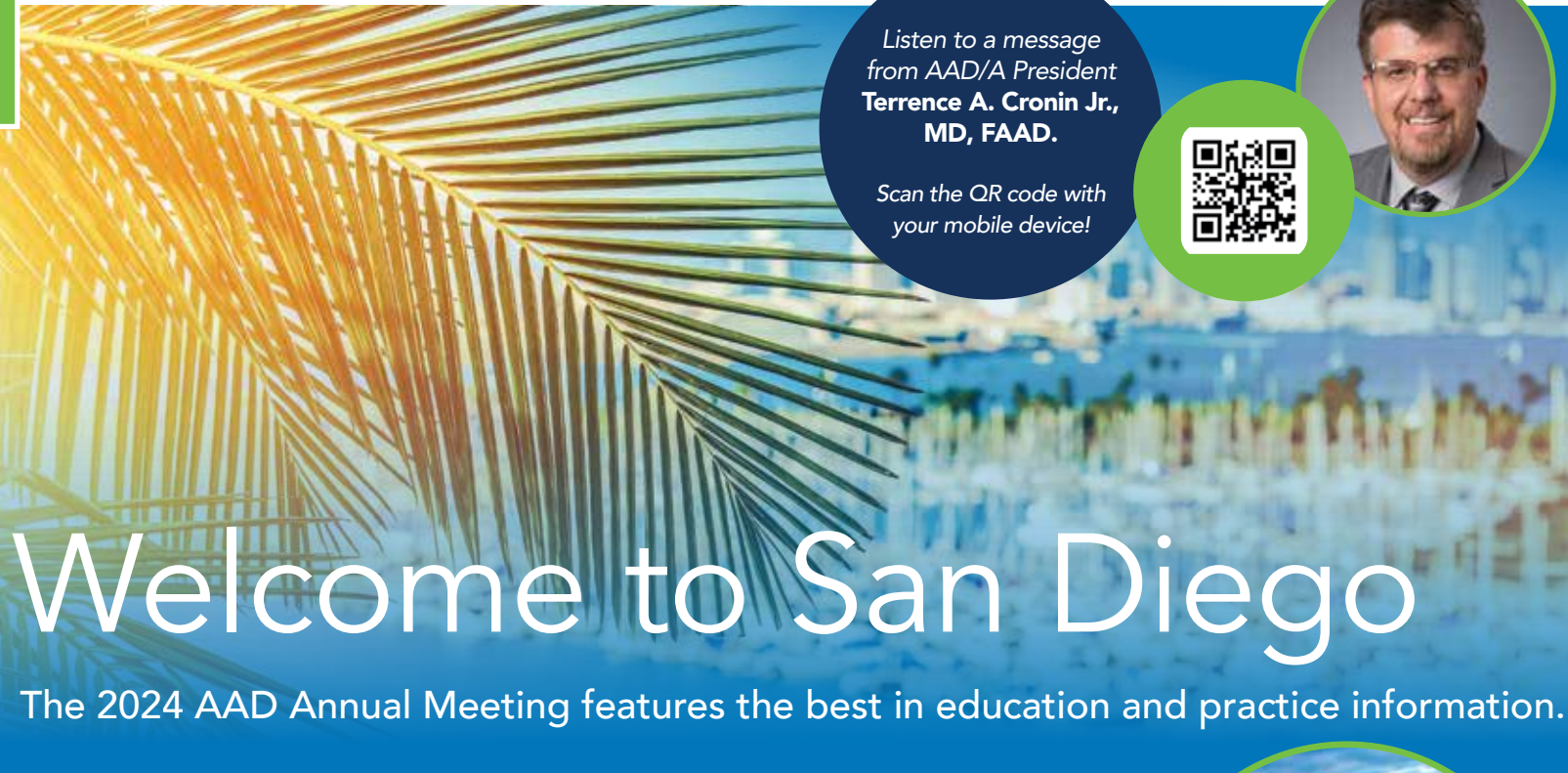
WHAT'S HOT?

Friday, March 8
9 a.m.-noon
S004 – Hot Topics
Location: Room 20B

This year's 'Hot Topics' will ignite your practice. Learn what's new and the most relevant to your practice in cosmeceuticals, alopecia, biologics and psoriasis, atopic dermatitis, melanoma, acne, and dermatologic surgery. Kenneth Tomecki, MD, FAAD, will moderate this morning's popular symposium.



Daylight Saving Time (DST) begins Sunday!
Turn your clocks forward an hour on Saturday night and don't miss a session!



Welcome to San Diego

The 2024 AAD Annual Meeting features the best in education and practice information.

Listen to a message from AAD/A President **Terrence A. Cronin Jr., MD, FAAD.**

Scan the QR code with your mobile device!



The world's largest dermatology meeting begins today in San Diego with the start of the 2024 AAD Annual Meeting, March 8-12. This will be the AAD's first meeting in San Diego since its record-breaking meeting in 2018, and the 2024 meeting is larger than ever — with more than 300 sessions to choose from and more than 10,000 medical personnel in attendance. The meeting delivers more education, valuable practice information, and networking opportunities than any other meeting in the specialty.

The Academy's large offering of education, networking, and other meeting-related events includes sessions you have been looking forward to, like Big Rashes in Little Patients, Hair Loss From Trichoscopy to Therapy, Controversies in Acne and Rosacea, Dermatologic Surgery: Cosmetic Tips and Pearls, Hand and Foot Psoriasis, and Alopecia: Work-Up and Treatment. You can

also look forward to two Late-Breaking Research sessions and two hands-on courses.

There are more than 40 new sessions, with titles including Lasers and Energy Devices in the Treatment of Acne, Treating the "Outsides" of the Inpatient: Pediatric Consults for the General Dermatologist, Giving a Great Talk: On Zoom or in the Room, Navigating Uncharted Waters: The Management of Autoimmune and Inflammatory Skin Disorders in Pregnant and Breastfeeding Patients, and Hair Loss and Health in Black Women.

Today features more than 90 sessions, including the ever-popular Hot Topics, Conquer the Boards, two new live demonstration courses, and several practice management sessions. The AAD Career Networking Event is also today.

Saturday has more than 90 sessions and includes a Late-Breaking Research session, the Resident and Fellows Symposium,

Resident Jeopardy, and Young Physician Pearls and Pitfalls.

On Sunday, be sure to attend the Annual Business Meeting, followed by a full Plenary session with expert speakers presenting on a variety of topics as well as guest speaker William Shatner, award-winning actor, director, producer, writer, and recording artist. There's another Late-Breaking Research session on Sunday as well as Boards and Beyond, and scores of other topics.

Monday has more than 60 sessions including several hands-on sessions. And, of course, the meeting ends with two great sessions on Tuesday.

Save some time to see the more than 350 exhibiting companies in the Exhibit Hall, and make sure to stop by the AAD Resource Center, Booth 739, to learn more about your member benefits and save on practice management resources, patient handouts, and professional education activities. ●



With its scenic waterfront location, the San Diego Convention Center has been a perennial favorite among attendees. It's located within an area rich with history, culture, and attractions. Balboa Park, the nearby Gaslamp Quarter, La Jolla, Pacific Beach, the San Diego Zoo, and the USS Midway Museum are just a few of the many local highlights of the area. San Diego is home to approximately 7,000 restaurants and more than 150 craft breweries.



Enhanced searchable online program now available

Easily search and identify sessions by date, time, and topic, or by ticketed or restricted events. Filter to find new sessions, meet MOC requirements, or cover practice management topics, and more. Visit <https://am2024.aad.org/sessions>. Bookmark it today!

Inside

Hormonal therapies for acne and androgenetic alopecia **3** Frontal fibrosing alopecia misunderstood and rising **6** Social media **7** Locals share the secrets of San Diego **8** 2024 Gold Medal Award **10** Growing treatments for non-growing hair **15** AAD Resource Center **16** Learning to lead and the basics of business **22**

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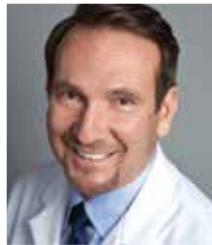
Hormonal therapies for acne and androgenetic alopecia

A plus for men and women.

▶ **U046 – The Role of Topical Therapies Involving Androgen Hormones in Acne and Androgenetic Alopecia (AGA)**
4:30-5:30 p.m. | Saturday, March 9
Location: Room 6B



Lawrence J. Green, MD, FAAD, clinical professor of dermatology at the George Washington University School of Medicine in Washington, D.C.



Ken Washenik, MD, PhD, FAAD, medical director of the Bosley Medical Group in Beverly Hills and faculty member in the Ronald O. Perelman department of dermatology at the NYU Langone School of Medicine

Hair follicles, the skin's epidermal layer, and sebaceous glands are among the body's most androgen-responsive tissues. Saturday's session, U046 – The Role of Topical Therapies Involving Androgen Hormones in Acne and Androgenetic Alopecia (AGA) will explore the prominence androgens play in skin and hair health.

Dermatologists now have access to an array of oral and topical treatment options for acne and AGA that target androgen receptors, with many more in development. Session director Lawrence J. Green, MD, FAAD, clinical professor of dermatology at the George Washington University School of Medicine in Washington, D.C., will lead the discussion on the role of androgens and other hormones in the pathogenesis of acne and AGA, the latest clinical evidence regarding topical and anti-androgen treatments for acne and AGA, and new topical and oral anti-androgen therapies available and under investigation.

"Skin is a peripheral organ that locally synthesizes significant amounts of androgens. Hair growth and sebum production are also highly androgen regulated," Dr. Green said.

New hope for a predominant condition

Acne vulgaris is one of the most common skin conditions, affecting more than 90% of the world population. The role of anti-androgen medication for acne has been recognized with oral spironolactone, an androgen receptor blocker, the most widely used for females with hormone acne pattern related to their menstrual cycle around the chin, jawline, and neck. But an emerging approach to consider, Dr. Green said, is the long-term use of spironolactone for treating all types of acne, including on the back, chest, and forehead in females of all ages.

Dr. Green will also discuss the new kid on the block: clascoterone (cortisolone 17alpha propionate), the first topical androgen antagonist developed to treat acne in both male and female patients and the only such agent to receive FDA approval for treatment of acne in patients

12 years of age and older. Hormonal therapy can be effective and potentially safer for long-term use for treating acne compared to oral antibiotics.

Benefitting men and women equally

"Clascoterone binds to the androgen receptor and inhibits androgen-related lipid and cytokine productions," he said. "The hope is that we'll start using more clascoterone in our treatment armamentarium for men and women with acne and spironolactone for women long-term because it encourages antibiotic prudence."

Although clascoterone has been approved for the treatment of acne, it's still in the clinical trial phase for male and female pattern hair loss, said session panelist Ken Washenik, MD, PhD, FAAD, medical director of the Bosley Medical Group in Beverly Hills and a faculty member in the Ronald O. Perelman department of dermatology at the NYU Langone School of Medicine. Dr. Washenik will discuss the potential promise of topical androgen modulating drugs for AGA.

An optimistic outlook

"We are following the development of potent androgen receptor blockers that will have minimal or no systemic androgen modulating effect and the topical use of the 5-alpha reductase inhibitor, finasteride," Dr. Washenik said. "It is used off-label by some practitioners in the U.S., but no topical formulation has been approved by the FDA. The topical use of finasteride has been approved in Europe. Topically active androgen modulators, including androgen receptor blockers, androgen receptor degraders, and 5-alpha reductase inhibitors are an active area of drug research. I remain optimistic we'll see more promising topicals in the not-too-distant future."

Tomorrow afternoon's session will also include Adelaide A. Hebert, MD, FAAD, who will discuss the role of topical therapies involving androgen hormones in acne; and Maryanne Makredes Senna, MD, FAAD, who will discuss the role of androgens in female pattern hair loss and AGA pathogenesis. ●



What are you looking forward to at the 2024 AAD Annual Meeting?

"For the 2024 AAD meeting in San Diego, I am looking forward to checking out **Nail Surgical Techniques Made Simple** and **Malignant Melanoma: Molecular Diagnostics, Emerging Therapies, and the Microbiome**. I'll also definitely be attending the board exam prep courses!"

— Tim "DUTCH" Holland, DO, Maj, USAF, Naval Medical Center San Diego



"This year, I'm most excited to hear about late-breaking updates in **targeted therapy for a variety of chronic dermatologic diseases!** While I could say something similar for most years, we are truly in the midst of an innovation revolution — gone are the days of dermatology being thought of as a specialty of topical corticosteroids and few other options."

— Raj Chovatiya, MD, PhD, MSCI, FAAD



"At the 2024 AAD Annual Meeting, I eagerly anticipate the **new session Quick Fire Surgical Pearls**, where, as a resident, I can learn practical surgical tips by experienced faculty to enhance my training. I'm very excited to continue learning effective and efficient practices like designing repairs for functional and cosmetic benefit and optimizing my patient's overall outcome and experience."

— Jessica Kaprive, DO, PGY-3 dermatology resident



"There are so many amazing sessions planned for the 2024 AAD Annual Meeting! One that I'm especially excited to attend is **Granulomatous Disorders of the Adult Skin** led by Misha Rosenbach, MD, FAAD. Also at that session, University of Wisconsin's very own Bridget Shields, MD, FAAD, will be speaking on Crohn's/inflammatory bowel disease! I'm looking forward to seeing the speakers and all my colleagues there!"

— Kristen Chen, MD



"The AAD Annual Meeting is the hallmark event for all dermatologists. It's where you can hear from expert leaders in our dermatology community discussing the latest and best treatments for new conditions in dermatology, particularly in the **Late-Breaking Research** sessions. It's also great to reunite with old friends and meet new partners in our field. This year in sunny San Diego will be one for the books."

— Maryam Safaee, MD, FAAD





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HAPPENING TODAY

Frontal fibrosing alopecia misunderstood and rising

The push for research and treatment is on.



Isabella Doche, MD, PhD, IFAAD, researcher at the University of Sao Paulo in Brazil



Maria K. Hordinsky, MD, FAAD, professor and chair of the department of dermatology at the University of Minnesota Medical School in Minneapolis

F033 – Unraveling Frontal Fibrosing Alopecia: Current Landscape and Challenges
3:30-5:30 p.m. | Friday, March 8
Location: Room 6F

Frontal fibrosing alopecia (FFA) — first described in postmenopausal women in the mid-1990s — has since expanded to include men and premenopausal women. Considered a misunderstood disease, FFA rates are rising across the globe, and epidemiologic research in FFA has been hampered by not having an ICD-10-CM code.

Today, FFA is considered a generalized disease that can have diverse scalp and non-scalp features, such as facial papules, depressed or raised forehead veins, and loss of eyebrow fibers. Growing concern over FFA is the foundation for this

afternoon's session, F033 – Unraveling Frontal Fibrosing Alopecia: Current Landscape and Challenges. Session speakers Maria K. Hordinsky, MD, FAAD, a professor and chair of the department of dermatology at the University of Minnesota Medical School in Minneapolis, and Isabella Doche, MD, PhD, IFAAD, a researcher at the University of Sao Paulo in Brazil, will explore the condition, current treatments, research, and new technology to assess and monitor therapeutic outcomes.

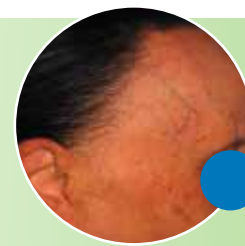
“In the past few decades, there has been an increase in the number of FFA cases, particularly in Western

countries,” said Dr. Hordinsky. “This has led investigators to look for environmental triggers, such as in cosmetic products, as well as the possibility of hormonal disruption by endogenous or exogenous factors, including dioxins. In its early presentation, FFA may appear as androgenetic alopecia or alopecia areata. The correct diagnosis may not be readily apparent for a variety of reasons, including not pulling the hair back during the clinical examination to expose not only the recession of the frontal hair line but also the characteristic perifollicular erythema and scale seen in FFA.”

Getting it right: Dr. Doche said even normal-appearing areas of the scalp may be affected and the condition can be seen in the lower occipital scalp.

Often, she said, if the hair is not pulled up to examine this region, the diagnosis may be missed. Dr. Hordinsky added that FFA can occur with other hair diseases, such as female or male androgenetic alopecia.

An accurate FFA diagnosis can be difficult, Dr. Doche said, because it shares many histologic features with the scarring alopecia lichen planopilaris (LPP), and it is still considered by many to be a variant of LPP. However, clinical and pathological differences have now been identified. Genetics can be a contributing factor as well. The average age of onset of FFA has typically been between 56 and 66 years of age, but it is now presenting in younger adults.



Frontotemporal and eyebrow hair loss associated with prominent facial veins



Male patient lacking sideburns with facial erythema



Long-standing disease with severe frontal hairline recession



Facial hyperpigmentation and erythema



Facial papules

“At the first visit, the primary goal is to stabilize the disease process,” Dr. Hordinsky said. Dr. Doche concurred. **“Once the disease has been stabilized, hair growth-promoting medications and devices can be recommended to try to regrow hair.”**

Halt the inflammation

Treating the condition is a multistep approach.

“At the first visit, the primary goal is to stabilize the disease process,” Dr. Hordinsky said. Dr. Doche concurred. “Once the disease has been stabilized, hair growth-promoting medications and devices can be recommended to try to regrow hair. Treatments for FFA include anti-inflammatory and immunosuppressant drugs, such as hydroxychloroquine, corticosteroids, and doxycycline, topical medications, and intralesional steroids,” Dr. Doche said. “New approaches such as platelet rich plasma (PRP), phototherapy, lasers, oral minoxidil, topical gabapentin, and low-dose naltrexone have been used with varying results. Antiandrogens such as dutasteride have also been found to be beneficial to some patients.”

According to Dr. Doche, patient follow-up is one of the most challenging parts of the medical approach. Videodermoscopy or handheld dermoscopy of the scalp (also known as trichoscopy) can be extremely helpful, especially in the early stages of the disease, to better evaluate subtle signs of inflammation as redness, scaling, and fractured hairs. Measuring hair line recession using technologies such as Hair Metrix (Canfield Scientific) or Fotofinder can be useful to establish a baseline of disease extent and inflammation. That allows dermatologists to engage with the patient and evaluate the course of treatment.

The need for more research

Small research studies with topical or oral JAK inhibitors are currently underway and results are pending, according to Dr. Hordinsky. However, FFA research has been challenging in the U.S. as the condition lacks its own ICD-10 code.

“This is now changing with the recent efforts of a group of dermatologists, some current dermatology residents, and medical students. There will now be a code for this disease in October 2024,” Dr. Hordinsky said.

Other FFA research on neurogenic inflammation as well as the study of the immune target on the hair follicle continues, Dr. Doche said. However, she urged more clinical research as this is a unique disease, and more patients are being diagnosed.

Finally, Dr. Doche encourages dermatologists to understand and address the psychological aspects in the management of this disease. ●

Step 1: Treat inflammation

Tier 1 treatments

- Topical, high-potency corticosteroids/intralesional steroids
- Topical, non-steroid anti-inflammatory creams (tacrolimus, pimecrolimus, JAK inhibitors)
- PBM phototherapy

Tier 2 treatments

- Hydroxychloroquine
- Low-dose antibiotics for anti-inflammatory effect
- Acitretin

Tier 3 treatments

- Cyclosporine
- Mycophenolate mofetil
- Prednisone
- Oral PPAR-γ-agonist, pioglitazone hydrochloride
- JAK inhibitors

Follow @AADmember to win big at Annual Meeting!

What could be better than being in San Diego with all your favorite colleagues? Winning daily giveaways, of course! The @AADmember accounts are hosting new **social media challenges** each day of the **2024 AAD Annual Meeting, from Friday, March 8, until Monday, March 11.**

Each day, a post will be shared on Instagram and X (formerly Twitter) that will ask attendees to participate in a new type of challenge. One randomly selected winner will be chosen on each platform to receive a daily giveaway. Prizes will include everything from \$100 gift cards to registration discounts for future AAD meetings. Attendees are encouraged to participate

on both platforms to double down on the fun and increase their chances of winning. In addition to offering sizzling prizes, the @AADmember accounts will also be sharing tons of photos and updates about the meeting that you won't want to miss. Be sure to include the official meeting hashtag **#AAD2024** in all your posts to see if your content gets reshared by the AAD! ●

For more information, see the official rules and regulations online at aadmeetingnews.org/22886745 or direct message @AADmember on X (formerly Twitter) or Instagram.



#AAD2024



TODAY'S HIGHLIGHTS

S018 – Psoriasis
1-4 p.m.
Location: Room 20B

S019 – Nail Symposium
1-4 p.m.
Location: Room 23C

S020 – Treating Severe Skin Diseases in Children
1-4 p.m.
Location: Room 8

S021 – Translating Evidence Into Practice: Primary Cutaneous Melanoma Guidelines
1-4 p.m.
Location: Room 28D

S022 – Alopecia Areata: New Therapies
1-4 p.m.
Location: Room 20A

Battling social media misinformation



Ronda Farah, MD, FAAD



Sara Moghaddam, MD, FAAD



Oyetewa Oyerinde, MD, FAAD

With more and more patients turning to social media for health care information, it's become increasingly important for dermatologists to be a credible source of information and combat misinformation on the platform. Learn how to take your social media efforts to the next level in a new session F126 – Combatting Misinformation and Positioning the Specialty on Social Media on Saturday, March 9, from 1 to 3 p.m. in Room 6B. The session includes presentations by AAD Social Media Correspondents Ronda Farah, MD, FAAD, Sara Moghaddam, MD, FAAD, and Oyetewa Oyerinde, MD, FAAD. ●

"We are so excited to bring the tips we have learned as social media correspondents for the Academy to our colleagues. We now have nearly two years of real world experience and data that has come out of the AAD social media initiative and we are ready to share it with the members. This session is also a great session for those wanting to launch social media for the first time or to reinvigorate their current platforms."

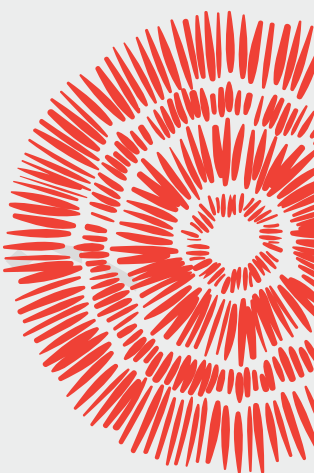
– Ronda Farah, MD, FAAD

F126 – Combatting Misinformation and Positioning the Specialty on Social Media NEW
1-3 p.m. | Saturday, March 9
Location: Room 6B



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San Diego hidden gems!

Locals share the secrets of San Diego.



San Diego is a friendly city, known for its tacos, beaches, and perfect weather. If you're looking to explore or catch a breather between the high-yield lectures and bustling Exhibit Hall, check out these hidden gems, recommended by local dermatology residents from Naval Medical Center San Diego!

Back Row: Shaun Ostrofe, DO, PGY-3; Austin Park, MD, PGY-4; Tim Holland, DO, PGY-3; Dave Kirwin, MD, PGY-2; Monica Borza, DO, PGY-2;
Front Row: Travis Frantz, MD, PGY-2; Kat Kramer, MD, PGY-3; Aly Brahe, MD, PGY-4; Alex Pybus, MD, PGY-2



Food and drink

Bronx Pizza | 111 Washington St. • The Taco Stand | 645 B St.

For the best pizza in San Diego, check out Bronx Pizza in Hillcrest (cash only). There's a reason why Dave Portnoy of Barstool Sports rated this place an 8.1 (a high score for a pizza place on the West Coast). The Taco Stand has a few locations in San Diego and offers up excellent Tijuana-style street tacos. I highly recommend the Al Pastor and the Nopal tacos.

– Tim Holland, DO, PGY-3

Animae | 969 Pacific Highway

For a fine dining experience that is more than worth the hype, make a reservation for dinner at Animae. This restaurant in the Gaslamp is a beautiful blend of Art Deco style, West Coast Steakhouse, and Asian culinary influences. Start with the Hunan Lamb Chops, Crispy Potatoes, and work your way to the A5 Wagyu. You'll dream of this meal for years to come.

– Aly Brahe, MD, PGY-4

Bali Hai | 2230 Shelter Island Drive

Check out Bali Hai Polynesian eatery for a world-renowned Mai Tai, seafood dishes, and enchanting bay views.

– Dave Kirwin, MD, PGY-2

The Red Door | 741 W Washington St.

This is one of my favorite restaurants in San Diego. Head chef and owner Luciano Cibelli personally makes sure your meal is enjoyable, and you truly can't go wrong with a menu packed full of Italian-inspired comfort food. Their handcrafted cocktails are delightful. Make sure you reserve a table!

– Alex Pybus, MD, PGY-2

Rocky's | 3786 Ingraham St. • Taco Surf PB | 4657 Mission Blvd.

Rocky's has the best burger in town. Head over to the Crown Point area of Pacific Beach. Make sure you bring cash! While in Pacific Beach, check out Taco Surf for the best rolled tacos as rated by San Diego Magazine.

– Shaun Ostrofe, DO, PGY-3

Experiences

San Diego tidepools

Unlike summer when low tide falls at night, afternoon low tides in early March are a great time to check out local tidepools and find crabs, anemones, urchins, turban snails, sculpin, and maybe even an octopus or starfish! Check out the Point Loma Tidepools, Tide Beach Park in Solana Beach, or Dike Rock in La Jolla.

– Kat Kramer, MD, PGY-3

Rent a bicycle and explore Coronado

Experience breathtaking views of downtown San Diego from the waterfront, stop by the beach and Hotel Del Coronado, and finish off with a meal at Clayton's Diner.

– Austin Park, MD, PGY-4

La Jolla Cove sea lions

For a unique wildlife experience, take the young and grown children to La Jolla Cove to view the seals and sea lions. While at the Cove, you can also pop over to Brockton Villa for a delicious brunch!

– Shaun Ostrofe, DO, PGY-3

Torrey Pines State Natural Reserve

This park is rich in history and natural beauty. Don't miss the opportunity to hike to the top of the iconic cliffs of La Jolla, feeling the California sunshine on your face (with plenty of your favorite sunblock of course) and the sand between your toes on a relaxing beach walk.

– Travis Frantz, MD, PGY-2

Little Italy

Charming, pedestrian-friendly neighborhood filled with live music, patio cafés, restaurants, pubs, and shops! Best coffee: Lofty Coffee. Best breakfast: Morning Glory. Best apps: Juniper and Ivy. Best entrées: Barbusa (get the pesto gnocchi). Best cocktails: Born and Raised. Best atmosphere: Nolita Hall. Best dessert: Salt and Straw. And don't miss the famous farmers market on Saturday!

– Monica Borza, DO, PGY-2

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2024 Gold Medal Award

What do you think your greatest contribution to the specialty has been?

“My greatest contribution to our specialty has been my unrelenting advocacy for over four decades to obtain appropriate coverage and reimbursement for the services and procedures we perform so that our patients can receive the highest quality care.”

Clifford Warren Lober, MD, JD, FAAD
2024 Gold Medal Recipient

The Gold Medal award is the Academy's highest honor. It is presented on a highly selective basis in recognition of outstanding and exceptional service to the specialty of dermatology in the science, teaching, and practice of cutaneous medicine and surgery. It is also considered for those who have made an outstanding and exceptional contribution to the administrative aspects of this specialty, nationally or internationally.

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Scan the QR code for instant access to daily articles, photos, and late-breaking research from the Annual Meeting.

aadmeetingnews.org



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American Academy of Dermatology

PRESIDENT'S GALA

2024 President's Gala Supporters

The American Academy of Dermatology would like to thank these generous sponsors of the 2024 President's Gala for their support of the Academy's community outreach and patient education initiatives that benefit the lives of patients, local communities, and the Academy members who serve them.























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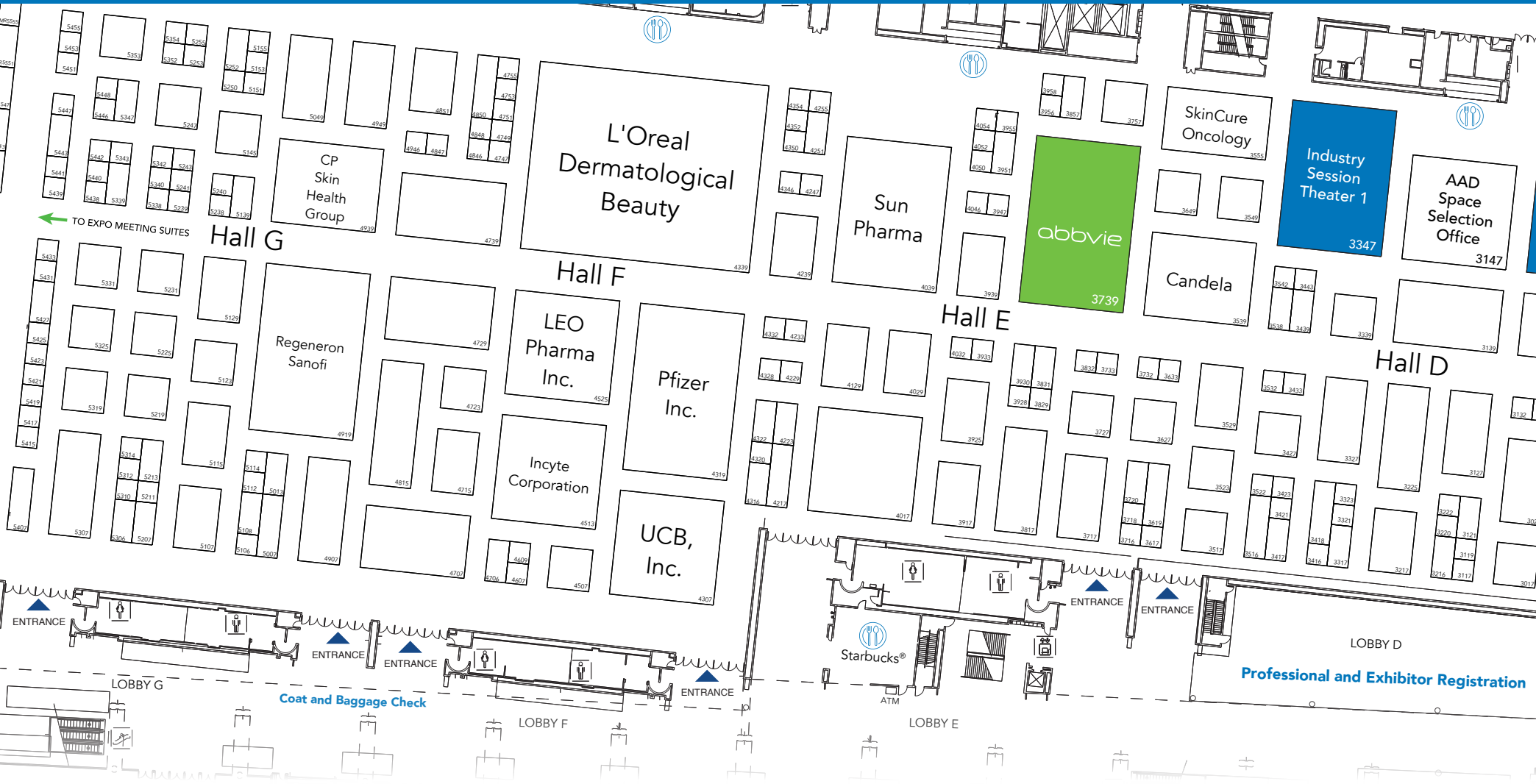
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Exhibit Hall Map



Exhibit Hall hours
 Friday-Saturday | 10 a.m.-5 p.m.
 Sunday | 10 a.m.-3 p.m.



Exhibitor Listing

Data current as of Feb. 23, 2024. Please use the AAD Meeting App aad.org/mobile for the most up-to-date exhibitor list.

123 - D

3Gen, Inc./DermLite 3817
 5CC (5-Continent-Congress) 3947
 AAD Industry Product Theater 1 3347
 AAD Industry Product Theater 2 2947
 AAD Resource Center 739
 AAD Space Selection Office 3147, 3649
 AbbVie 3739
 ABISA 2128
 Acclaro Medical 2862
 Accurate Manufacturing, Inc. 5439
 AccuTec Inc. 1820
 Ace Medical Industry Co, LTD 958
 ACELYRIN, INC. 1452
 Acuderm 3939
 Advalight 4233
 Advanced Dermatology &
 Cosmetic Surgery 4223
 Aeon Biotherapeutics Corp. 4255
 Aerolase 1711
 Aesthetic Guide, The 1818
 AIM Medical Inc 1758
 Allergan Aesthetics 1639, 1811
 Alletess, Inc. 4749
 ALMIRALL 2917
 Alphyn Biologics, Inc. 2656
 Altus Biologics 1342
 AlumierMD 5443
 American Board of Dermatology 738

American Society for
 Dermatologic Surgery 2938
 Amgen, Inc. 2439
 AMLo Biosciences 4847
 AMP Medical Products, LLC 5310
 AnteAGE MD by Cellese 3857
 APDerm 1245
 Aqua Dermatology 3951
 Aquavit 1425
 Arcutis Biotherapeutics, Inc. 4815
 argenx 3421
 ASTERASYS Co LTD 2461
 Avantik 1340
 Aven, Inc. 730
 Avita Medical 2512
 Balassa Laboratories, Inc. 2516
 Bank of America Practice Solutions 742
 Barnet Products 5446
 BDSC Company 857
 Beiersdorf, Inc. 3139
 Beijing HUEFUL Technology Co., LTD 752
 Beijing Syntech Laser Co., Ltd. 3928
 Belle.ai 4054
 Benefis Health System 5442
 Benev Company Inc. 1211
 Biofrontera, Inc. 5331
 Biogened S.A. 2057
 Boehringer Ingelheim
 Pharmaceuticals, Inc 3017, 4017, 5353

Bristol-Myers Squibb 939, 2130
 Brymill Cryogenic Systems 2839
 Burton Medical, LLC 1359
 Burt's Bees 3217
 Caliber Imaging & Diagnostics 3439
 Candela 3539
 Canfield Scientific 2039
 Cantabria Labs 5049
 CareCredit 3517
 Casio America, Inc 5339
 Castle Biosciences 1419
 Celldex Therapeutics 751
 Chemistry Rx 1347
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HAPPENING TODAY

Growing treatments for non-growing hair

Clinical experience with new therapies offers more targeted and effective approach.



Natasha Atanaskova Mesinkovska, MD, PhD, FAAD, vice chair of dermatology clinical research at the University of California-Irvine

▶ **S022 – Alopecia Areata: New Therapies**
1-4 p.m. | Friday, March 8
Location: Room 20A

New therapies are on the rise for alopecia areata, the most common cause of immune-mediated alopecia that affects 2% of the U.S. population and strikes at the core of a patient’s self-esteem.

Natasha Atanaskova Mesinkovska, MD, PhD, FAAD, vice chair of dermatology clinical research at the University of California-Irvine, said Janus kinase (JAK) inhibitors are among the newest

treatments being used. Specifically, the FDA has approved baricitinib for patients 18 and older, and ritlecitinib for patients 12 and older.

“We are living in a most exciting moment for alopecia areata with the advent of new therapies with terrific efficacy and closely monitored evidence on their safety,” Dr. Mesinkovska said. “These medications are orally available and have short half-lives. They have been approved for use in ages 12 and above.”

Dr. Mesinkovska will lead a panel of experts in a discussion of those treatments, the pathology of alopecia areata, and therapeutic options in this afternoon’s session, S022 – Alopecia Areata: New Therapies.

The ideal candidate

One of the keys to these new treatment options, Dr. Mesinkovska explained, lies in knowing who is eligible to use them, as they might not be best for everyone.

“It is important to learn who the

patients are who will respond well and to try to delineate what to use from the newly available options,” she said. “Especially in children and women of child-bearing age.”

A guiding light

That is where therapeutic guidelines come into play. The AAD recommends differing treatment plans depending on multiple factors, including how long the patient has been experiencing hair loss, the age of the patient, and the severity of the condition. Dr. Mesinkovska said — in all instances — it is important to begin treatment as early as possible.

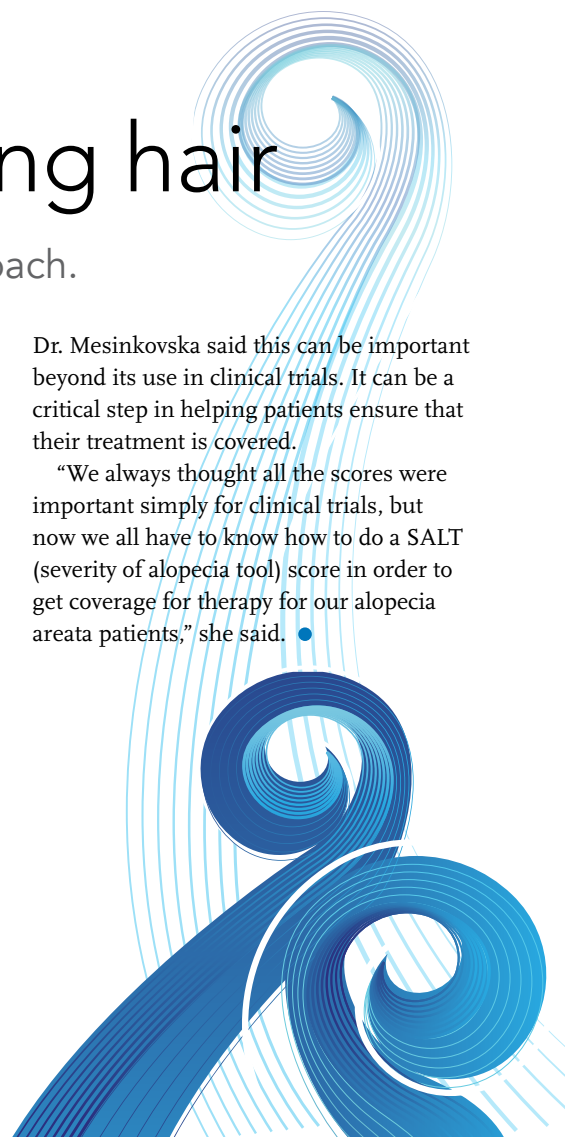
“The goal [of the guidelines] is to make dermatologists aware that early treatment leads to better quality of life for patients,” she said.

Recipe for success: Add SALT

One tool that dermatologists should have in their arsenal for treating alopecia areata is the alopecia areata severity scale.

Dr. Mesinkovska said this can be important beyond its use in clinical trials. It can be a critical step in helping patients ensure that their treatment is covered.

“We always thought all the scores were important simply for clinical trials, but now we all have to know how to do a SALT (severity of alopecia tool) score in order to get coverage for therapy for our alopecia areata patients,” she said. ●



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Location

Exhibit Hall, Booth 739

Hours

10 a.m.-5 p.m. | Friday, March 8

10 a.m.-5 p.m. | Saturday, March 9

10 a.m.-3 p.m. | Sunday, March 10

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10 a.m.-5 p.m. | Friday, March 8, and Saturday, March 9

10 a.m.-3 p.m. | Sunday, March 10

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Board Prep Plus

11 a.m.-noon | Friday, March 8

Take a test drive of the only question bank in dermatology you'll need to study for the boards. Individual and institutional pricing available.



Your Dermatologist Knows

12-1 p.m. | Friday, March 8

See details on page 17.

Dialogues in Dermatology podcast — Meet the editors

1-2 p.m. | Friday, March 8

Meet the Editorial Board, the voices behind our popular podcast. Residents stop by to sign up for your complimentary subscription during residency. Light refreshments, free gift while supplies last!



DataDerm™ drop-in hours

3-4 p.m. | Friday, March 8, and Saturday, March 9

Learn how DataDerm™ can help you assess and optimize care, avoid penalties, and advance the specialty.

Coding Power Hour

1:30-2:30 p.m. | Sunday, March 10

Get your coding questions answered by our experts – no appointment necessary! While you're here, don't forget to purchase your 2024 coding resources.

First-time attendees

Pick-up a special ribbon to add to your badge so others can help you navigate and make the most of your first AAD Annual Meeting.

Special member recognition

Have you been a member of the AAD for 30, 40, or 50 years? Pick up your milestone lanyard any time in the Resource Center! Just come to the main counter.

A Taste of AAD Innovation Academy

10 a.m.-1 p.m. | Friday-Sunday

Something is brewing this summer in Seattle! Grab a coffee, learn more about the educational meeting of the summer, and **enter for a chance to win FREE registration!**



Navigate your future
with confidence.

Attend the AAD Career Fair

- Grow your network
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FREE
to
Attend!

March 8, 2024
4:30 – 6:30pm PST

Marriott Marquis San Diego Marina
The Grand Ballroom 3/4/6

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Your Dermatologist Knows

12-1 p.m. | Friday, March 8

AAD Resource Center



Stop by to learn about the AAD's widely successful consumer positioning strategy, Your Dermatologist Knows. Take a picture with our fun props and post it on your own social media channels to spread dermatology's message.

Advancing Patient Care in Chronic Spontaneous Urticaria

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Hilton San Diego Bayfront
Indigo Ballroom DH (Level 2)



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CO-CHAIR & PRESENTER

April W. Armstrong, MD, MPH
University of California, Los Angeles (UCLA)
Los Angeles, California



CO-CHAIR & PRESENTER

Jason K. Lee, MD, FRCPC, FAAAAI, FAAAAI
Specialist, Clinical Immunology and Allergy
and Internal Medicine
Toronto, Ontario, Canada



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Your vote matters!

You will be able to watch presentations by the candidates for Academy president-elect during the Business Meeting.

AAD/A Annual Business Meeting
8-8:45 a.m.
Sunday, March 10
Preceding the Plenary session
Room 20B

Keep informed about the next AAD election through the **AAD Election Connection** at www.aad.org/election.

Important dates:

March 9, 2024
AAD Election opens

March 23, 2024
AAD Election closes

March 25, 2024
AAD Election results announced

This IME program is provided by PVI, PeerView Institute for Medical Education.

This activity is supported by an educational grant from Sanofi and Regeneron Pharmaceuticals.

This program is independent and is not part of the official AAD Annual Meeting, as planned by its Scientific Assembly Committee.

This program does not qualify for AAD continuing medical education (CME) credit.

NOW AVAILABLE!



ZORYVE[®]
(roflumilast) topical foam, 0.3%

DOWN TO AGE 9

Effectively control seborrheic dermatitis and simplify treatment with a steroid-free foam.¹

One foam. Once a day. Anywhere.¹

SebDone.

DRAMATIC 77% IGA SUCCESS AT WEEK 8^{1,2}

Actor portrayal

Trial 203 and STRATUM studies evaluated ZORYVE (n=458) vs vehicle (n=225) once daily for 8 weeks in patients with seborrheic dermatitis. The primary endpoint was IGA Success at Week 8, defined as a score of *Clear* (0) or *Almost Clear* (1) and a ≥ 2 -grade improvement from baseline.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.¹

IGA = Investigator Global Assessment

A 2023 Arcutis survey of 93 adults diagnosed with seborrheic dermatitis found that an average of 15 products (including over-the-counter, alternative, and prescription treatments) were reportedly used on a yearly basis.²

INDICATION

ZORYVE foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION

ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions ($\geq 1\%$) include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

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

References: 1. ZORYVE[®] foam. Prescribing information. Arcutis Biotherapeutics, Inc; 2023. 2. Data on File. Arcutis Biotherapeutics, Inc.



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US-COM-154-00125 01/24

See the results at
zoryvehcp.com/foam



Brief Summary of Prescribing Information for ZORYVE® (roflumilast) foam, 0.3%, for topical use. See package insert for full Prescribing Information.

INDICATIONS AND USAGE

ZORYVE foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

DOSAGE AND ADMINISTRATION

Shake can prior to each use. Apply a thin layer of ZORYVE foam, 0.3%, once daily to affected areas on skin and/or scalp when they are not wet. Rub in completely.

Wash hands after application.

Avoid fire, flame, and smoking during and immediately following application.

ZORYVE foam, 0.3%, is for topical use only and not for ophthalmic, oral, or intravaginal use.

CONTRAINDICATIONS

ZORYVE foam, 0.3%, is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

WARNINGS AND PRECAUTIONS

Flammability

The propellants in ZORYVE foam, 0.3%, are flammable. Avoid fire, flame, and smoking during and immediately following application.

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 (Trial 203 and STRATUM), 683 adult and pediatric subjects 9 years of age or older with seborrheic dermatitis were treated with ZORYVE foam, 0.3%, or vehicle foam once daily for 8 weeks.

The combined trial population was 79% White, 11% Black, and 5% Asian; for ethnicity, 79% identified as non-Hispanic/Latino and 21% identified as Hispanic/Latino. Fifty percent (50%) were male and 50% were female. The median age was 41 years (range 9 to 87 years). The median body surface area (BSA) affected was 2.5%.

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ZORYVE foam, 0.3%.

Table 1. Adverse Reactions Reported in ≥1% of Subjects with Seborrheic Dermatitis Treated with ZORYVE Foam, 0.3%, for 8 Weeks in Trial 203 and Trial STRATUM

Adverse Reaction	ZORYVE foam, 0.3% (N=458) n (%)	Vehicle foam (N=225) n (%)
Nasopharyngitis	7 (1.5)	1 (0.4)
Nausea	6 (1.3)	0 (0)
Headache	5 (1.1)	0 (0)

The following additional adverse reactions were reported in fewer than 1% of subjects treated with ZORYVE foam, 0.3%: diarrhea and insomnia.

In 408 subjects who continued treatment with ZORYVE foam, 0.3%, for up to 24 to 52 weeks in an open-label, long-term trial, the adverse reaction profile was consistent with that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are insufficient data available on the use of ZORYVE foam, 0.3%, in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. 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 30 and 26 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 10 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 16 and 49 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 49 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

Avoid using ZORYVE foam, 0.3%, during labor and delivery. There are no human studies that have investigated effects of ZORYVE foam, 0.3%, 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 (30 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 (3 times 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 (10 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 (29 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 (26 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 (16 and 49 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 (16 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 (49 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 (97 times the MRHD on a mg/m² basis).

Lactation

Risk Summary

There are no data on the presence of roflumilast or its metabolite 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 be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZORYVE foam, 0.3%, and any potential adverse effects on the breastfed infant from ZORYVE foam, 0.3%, or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE foam, 0.3%, on the smallest area of skin and for the shortest duration possible while breastfeeding. To avoid direct infant exposure, advise breastfeeding women not to apply ZORYVE foam, 0.3%, directly to the nipple or areola. If applied to the patient's chest, avoid exposure via direct contact with the infant's skin.

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 foam, 0.3%, for the treatment of seborrheic dermatitis have been established in pediatric patients 9 years of age and older. Use of ZORYVE foam, 0.3%, in this age group is supported by data from two 8-week, vehicle-controlled trials which included 32 pediatric subjects 9 to 17 years of age, of whom 17 received ZORYVE foam, 0.3%, and from open-label trials of up to 52 weeks which included 23 pediatric subjects treated with ZORYVE foam, 0.3%. The adverse reaction profile was consistent with that observed in adults.

The safety and effectiveness of ZORYVE foam, 0.3%, in pediatric patients below the age of 9 years have not been established.

Geriatric Use

Of the 683 subjects with seborrheic dermatitis exposed to ZORYVE foam, 0.3%, or vehicle for up to 8 weeks in the controlled clinical trials, 98 (14%) were 65 years of age or older, and 33 (5%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Oral roflumilast 250 mcg once daily for 14 days was studied in subjects with hepatic impairment. The systemic exposure of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE foam, 0.3%, is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). No dosage adjustment is needed in patients with mild (Child-Pugh A) hepatic impairment.

PATIENT COUNSELING INFORMATION

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

Flammability

Because the propellants in ZORYVE foam, 0.3%, are flammable, instruct the patient to avoid fire, flame, and smoking during and immediately following application.

Lactation

Advise patients to use ZORYVE foam, 0.3%, on the smallest area of skin and for the shortest duration possible while breastfeeding. Instruct patients who are breastfeeding not to apply ZORYVE foam, 0.3%, directly to the nipple or areola to avoid direct infant exposure. Instruct patients to avoid inadvertent contact of treated areas with infant skin.

FOR PLAQUE PSORIASIS
AGE 6+

Z ZORYVE[®]
(roflumilast) cream 0.3%

Effective.
Everywhere.
Easy.¹

A once-daily, steroid-free cream with the **power to clear elbows and knees**, and the **gentleness for face and folds**.^{1,2}

Actor portrayal

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%. The primary endpoint was IGA Success at Week 8 and a key secondary endpoint was I-IGA Success at Week 8.¹

IGA Success and I-IGA Success were defined as a score of *Clear* (0) or *Almost Clear* (1) and a ≥ 2 -grade improvement from baseline.^{1,2}

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.¹

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

INDICATION

ZORYVE cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION

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 (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

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

References: 1. ZORYVE[®] cream. Prescribing information. Arcutis Biotherapeutics, Inc; 2023. 2. Data on File. Arcutis Biotherapeutics, Inc.

See the results at
zoryvehcp.com/cream



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US-COM-151-00311 01/24

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

INDICATIONS AND USAGE

ZORYVE cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

DOSAGE AND ADMINISTRATION

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

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

CONTRAINDICATIONS

ZORYVE cream is contraindicated in patients with 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 adult and pediatric subjects 6 years of age or older with plaque psoriasis were treated with ZORYVE cream or vehicle topically 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 an adverse reaction was 1.0% for subjects treated with ZORYVE cream and 1.3% for subjects treated with vehicle cream. The most common adverse reaction that led to discontinuation of ZORYVE cream was application site urticaria (0.3%).

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

Table 1. Adverse Reactions Reported in ≥1% of Subjects with Plaque Psoriasis Treated with ZORYVE Cream (and More Frequently than Vehicle Cream) for 8 Weeks in Trials DERMIS-1 and DERMIS-2

Adverse Reaction	ZORYVE Cream (N=576) n (%)	Vehicle Cream (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 cream for up to 64 weeks in open-label extension trials, the adverse reaction profile was consistent with that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are insufficient data available on the use of ZORYVE cream in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. 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 36 and 31 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 12 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 19 and 59 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 59 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

Avoid using ZORYVE cream during labor and delivery. There are no human studies that have investigated effects of ZORYVE cream 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 (36 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 (4 times 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 (12 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 (35 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 (31 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 (19 and 59 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 (19 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 (59 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 (116 times the MRHD on a mg/m² basis).

Lactation

Risk Summary

There are no data on the presence of roflumilast or its metabolite 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 cream and any potential adverse effects on the breastfed infant from ZORYVE cream or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE cream on the smallest area of skin and for the shortest duration possible while breastfeeding. To avoid direct infant exposure, advise breastfeeding women not to apply ZORYVE cream directly to the nipple or areola. If applied to the patient's chest, avoid exposure via direct contact with the infant's skin.

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 cream for the treatment of plaque psoriasis have been established in pediatric patients 6 years of age and older. Use of ZORYVE cream in pediatric patients 6 to less than 18 years of age is supported by data from two 8-week, vehicle-controlled safety and efficacy trials which included 18 pediatric subjects 6 to 17 years of age, of whom 11 received ZORYVE cream. Use of ZORYVE cream in pediatric patients 12 to 17 years of age is also supported by data from open-label trials of 2 and 24 weeks duration which included 18 pediatric subjects 12 to 17 years of age treated with ZORYVE cream. Use of ZORYVE cream in pediatric patients 6 to less than 12 years of age is also supported by data from one 4-week, open-label, safety and pharmacokinetic (PK) study which included 20 pediatric subjects 6 to less than 12 years of age. The adverse reaction profile in subjects 6 to less than 18 years of age was consistent with that observed in adults.

The safety and effectiveness of ZORYVE cream in pediatric patients below the age of 6 years have not been established.

Geriatric Use

Of the 881 subjects with psoriasis exposed to ZORYVE cream 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 systemic exposure of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE cream is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). No dosage adjustment is needed in patients with mild (Child-Pugh A) hepatic impairment.

PATIENT COUNSELING INFORMATION

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

Lactation

Advise patients to use ZORYVE cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Instruct patients who are breastfeeding not to apply ZORYVE cream directly to the nipple and areola to avoid direct infant exposure. Instruct patients to avoid inadvertent contact of treated areas with infant skin.

HAPPENING TODAY

Learning to lead and the basics of business

AAD leadership session schools dermatologists in both.

Learning on the fly alone is not a suitable approach for studying medicine. Yet, if you're a dermatologist, this is often the approach for learning the business aspects of the profession.

Patient care comes first. There comes a time, however, that every dermatologist needs to have a working knowledge of business and leadership roles and responsibilities across a wide spectrum of settings, according to Keyvan Nouri, MD, MBA, FAAD, professor of dermatology, ophthalmology, otolaryngology,

and surgery at the University of Miami Leonard M. Miller School of Medicine. Dr. Nouri is the director of today's session, S016 – Business and Leadership: What Dermatologists Should Know.

“One should have a comprehensive understanding of several business aspects within dermatology. This includes knowledge regarding the functioning of the U.S. health care system and its associated legal aspects,” he said. “Additionally, awareness of insurance companies, PBMs, pharmaceutical



S016 – Business and Leadership: What Dermatologists Should Know
1-4 p.m. | Friday, March 8
Room 26A

Keyvan Nouri, MD, MBA, FAAD, professor of dermatology, ophthalmology, otolaryngology, and surgery at the University of Miami Leonard M. Miller School of Medicine

companies, and the dynamics involved in patient-physician relationships is imperative.”

During the session, Dr. Nouri will take attendees on a journey through the pathways for

learning the business aspects of dermatology and medicine, outline various practice settings, and describe leadership perspectives in AAD and the American Medical Association (AMA).

The path to doing business

Various settings within the field

- Academic practice
- Individual private practice
- Group practices
- Practices based in community hospitals

Essential skills in this context involve

- Emotional intelligence
- Establishing strong rapport with patients
- Effective interpersonal communication
- Delivering exceptional patient care

Specialized business skills encompass

- Management
- Proficiency in accounting and finance
- Advocacy
- Understanding of government regulations such as HIPAA, OSHA, and the ACA

Also important is a good understanding of

- Consumer satisfaction and loyalty
- Repeat purchase
- Brand and innovation
- Efficient operations
- Legal considerations

Lean into leadership

For those who didn't get a foundation for business and leadership in school, Dr. Nouri encourages dermatologists to take advantage of councils, committees, and task forces for additional learning as well as the AAD's many Leadership Institute opportunities. These include the Leadership Forum, Academic Dermatology Leadership Program, and Advanced Leadership Program. Additionally, short courses are available at the AAD Annual Meeting and Innovation Academy.



ACTIVE PARTICIPATION in your state dermatology society and applying for committee and task force positions further contribute to making a meaningful impact.

LEADERSHIP FORUMS serve as interactive platforms to enhance knowledge and skills, fostering networking opportunities with colleagues.

Engaging in **ADVOCACY** provides avenues for mentorship from accomplished leaders, allowing collaboration to effect positive changes in the field of dermatology.



Leadership also develops through five characteristics, including:

1. Mentoring others
2. Challenging the status quo
3. Educating others
4. Creating opportunities for others
5. Practicing humility

Integrated learning

Several medical schools have begun integrating diverse leadership training initiatives, including combined MBA/MD programs. Engaging in various leadership roles within school organizations can provide students with valuable insights and expertise in this domain.

“The key takeaway is that business in medicine is very complex. Dermatologists, along with residents, fellows in training, and medical students must acquire knowledge in these areas to enhance patient care. By optimizing clinical care practices, we encourage promoting a focus on the well-being of both the individuals and the staff. Understanding these aspects is crucial to achieving the goal of delivering improved care for patients.”

– Keyvan Nouri, MD, MBA, FAAD



Remember to use the American Academy of Dermatology's (AAD) online Continuing Professional Development Transcript (CPD) Program to document your CME and MOC activities to send to a licensing body. This service is a member benefit at no additional fee.*

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