AAD

DermWorld meeting news

SATURDAY. MARCH 26, 2022

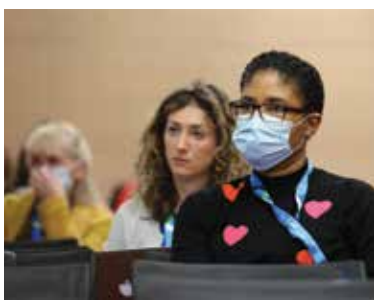
A Publication of the American Academy of Dermatology | Association

INSIDE ▶

MEET THE CANDIDATES 3 PATIENT SELECTION FOR PRP SUCCESS 4 2019 AAD/NPF GUIDELINES 8 WINDOW TO COVID-RELATED CLUES 10 TREATING DISEASES IN ALL SKIN COLORS 18 NEW APPLICATIONS IN PEDIATRIC DERMATOLOGY 20


Kieron S. Leslie, MBBS


Rita Khodosh, MD, PhD, FAAD (left)
Erin H. Amerson, MD, FAAD



The best defense in the age of biologics

Three speakers addressed testing and treatment for dermatologic disease in patients suspected of having COVID-19, HIV, hepatitis B and C, and tuberculosis. During Friday's U022 – Danger and Defense in the Age of Biologics, they also explored conditions under which treatment with biologics was recommended.

Because in many instances more definitive data, clinical trials, and guidelines are still needed, according to the speakers, the treatment discussion was predicated largely on available literature and the speakers' own experiences. Using case studies from their practices, they described the steps they took, revealed their experiences, and provided results for those cases.

Universally, they encouraged thorough testing as a starting point. Most dermatologists check their patients for underlying infections prior to starting systemic therapy, whether conventional immunosuppressants or biologic therapies. However, a positive test will require new disease management and treatment considerations.

"Immunosuppressives are not a significant risk factor for COVID-19 infection," said Kieron Leslie, MBBS, professor of dermatology at the University of California, San Francisco, and head of the HIV Dermatology Clinic at Zuckerberg San Francisco General Hospital. On the other hand, he said high-dose steroid use appears to increase the risk of infection.

He pointed to AAD guidance related to COVID-19, which simply says to continue immunosuppressives in patients who have not tested positive or exhibited symptoms of COVID-19, discontinue in patients who have tested positive for COVID-19, and restart when they have recovered.

Because patients with HIV are more susceptible to psoriasis and other inflammatory skin diseases, Dr. Leslie suggested topical therapy in mild-to-moderate cases, phototherapy, and antiretrovirals as first-line therapeutic agents in mild-to-severe cases, and oral retinoids for second-line treatment. For more severe disease, he said cautious use of cyclosporine, methotrexate, hydroxyurea, and tumor necrosis factor-α inhibitors may be considered.

Dr. Leslie said the optimal approach for immunosuppressive management in dermatology patients with HIV is to:

- optimize antiretroviral therapy
- consider non-immunosuppressive alternatives
- consult with the HIV/ID physician
- monitor the CD4 count/viral load

Erin Huiras Amerson, MD, FAAD, chief of dermatology service at Zuckerberg San Francisco General Hospital and UCSF clinical professor of dermatology, reviewed hepatitis B and C epidemiology, testing, and treatment.

She discussed drug choice (IL-12/23, IL-23, IL-17, and rituximab) and monitoring of patients with viral hepatitis who are initiating biologics and recommended when prophylactic antiviral treatment may be appropriate.

Detailing regimens for patients with tuberculosis, Rita Khodosh, MD, PhD, FAAD, vice chair and associate professor of the department of dermatology at the University of Massachusetts, said pretreatment latent tuberculosis infection (LTBI) testing is recommended for all psoriasis biologics.

Tumor necrosis factor inhibitors carry a high risk of tuberculosis reactivation. The risk may not be increased with IL-17 and IL-23 inhibitors. She also noted that shorter treatment regimens for LTBI are preferred due to the higher likelihood of completion. Biologics may be restarted one month after the initiation of LBTI treatment, she said. For active tuberculosis, biologics may be restarted after at least six months of treatment. ●

DON'T MISS POSTERS

Saturday, March 26
8:30 a.m. – 5 p.m.

Sunday, March 27
8:30 a.m. – 2 p.m.

Exhibit Hall:
Booth 001
Booth 002

Download the AAD Meeting app and gain access to:

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- Session evaluations
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2:11 PM !

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- X HEADACHE SETTING IN

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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 2022 Academy election of Officers, Directors, and Nominating Committee Member Representatives (West Region).

Visit the AAD Election Connection 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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Todd Schlesinger, MD, FAAD

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

Eligible voting members can vote by the personalized voting link sent by email or at the AAD Election Connection link. To request a PDF of the 2022 AAD Election ballot book, email candidates@aad.org. You can also print and fax your online secure election ballot starting March 26 to (877) 235-9052. Ballots received at the AAD office will be considered invalid.

Stay connected. Win big!

Attendees can participate in these two exciting social media challenges. Win free registration to either the 2022 AAD Innovation Academy in Vancouver, British Columbia, or the 2023 AAD Annual Meeting in New Orleans (winner's choice).

Twitter Pearl Challenge:
Tweet your top pearls or key takeaways from your favorite sessions with the hashtag **#AAD2022challenge**.

Instagram Photo Challenge:
Share a photo of yourself and/or colleagues while at the meeting with the hashtag **#AAD2022challenge**.

@AADmember

One random participant will be selected for each challenge. Each photo shared on Instagram and every tweet that includes the hashtag will be considered a valid entry — and there is no limit to how many entries an attendee can submit.

All entries must be submitted between 7 a.m. EST, March 25, and 11:59 p.m. EST, March 29. (AAD members only, U.S. or international).

Scan the QR code below to schedule COVID testing today

Testing is not a requirement but is available for those who need it for travel or are exhibiting symptoms. Reservations required.

PCR : $94 USD
Antigen: $35 USD
Same-day results.

Location: Room 050, adjacent to registration.

Pathways: Inclusivity in Dermatology

Pave the way

Support, share, and scan — it's that easy!

The American Academy of Dermatology, in collaboration with Johnson & Johnson Consumer Health and Janssen, is launching **Pathways: Inclusivity in Dermatology** to increase the number of practicing dermatologists who are underrepresented minorities in medicine (URiM). Through scholarship offerings, skills workshops, mentorship programs, and leadership training, **Pathways aims to increase the number of dermatology residents from Black, Latino, and Indigenous communities from approximately 100 residents to 250, or by over 50%, by 2027.**

How can you get involved while at the Annual Meeting?

Show your support
Visit the AAD booth #2529, the J&J Consumer Health booth #617, and Janssen booth #749 to pick up your Pathways lapel pin! Wear it with pride throughout the meeting.

Share your pathway story
We all have a story that led us to dermatology. Share your pathway story and inspire future dermatologists with **#DermPathways**

Scan this QR code
Learn more about the Pathways program by scanning the QR code below, or visit **www.aad.org/pathways**

WATER COOLER

What does this live AAD Meeting experience offer that you have been missing?

"The lectures, of course. Also, the value related to learning with and from people I have been on this journey with. I value the face-to-face relationships and nurturing them in person."

Jennifer David, DO, MBA, FAAD
Bensalem, PA

"Being able to see colleagues from Penn that I went to school with. I graduated in 2019, at the beginning of the COVID epidemic, and moved to Boston. Seeing and reconnecting with those colleagues has been wonderful."

Chrissy Cornejo, MD, FAAD
Boston

Patient selection key to PRP success

Omer Ibrahim, MD, FAAD, founder of Chicago Cosmetic Surgery and Dermatology

Platelet-rich plasma (PRP), a concentrate from whole blood, is widely discussed as one of the newest potential tools for skin and hair repair and also one of the most widely promoted dermatologic techniques on social media.

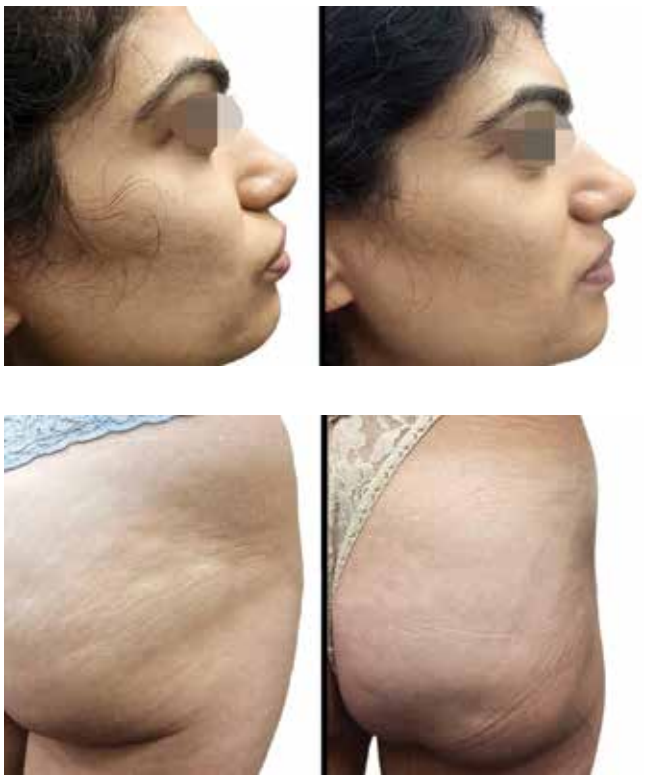
"There are people out there saying all you need is someone's blood and the right commercial system and you're in business," said session director Omer Ibrahim, MD, FAAD, during yesterday's new session, **F019 – Platelet Rich Plasma.** Dr. Ibrahim is founder of Chicago Cosmetic Surgery and Dermatology. "As dermatologists, we need to cut through the misinformation and get to the science behind PRP."

During the session, Dr. Ibrahim described what is known of the mechanism of action for PRP, how to prepare it, and how to select the most appropriate patients and administer PRP to the best effect.

True blood?

Long used in cardiac surgery, oral surgery, orthopedics, and other fields, PRP is a serum concentrate that contains a high volume of platelets and platelet-derived growth factors including vascular endothelial growth factor, epithelial growth factor, transforming growth factor beta, and insulin-like growth factor. These components promote stem cell regeneration, soft tissue remodeling, mitogenesis, and cell differentiation leading to cellular proliferation, collagen synthesis, and blood vessel formation that aid in the improvement of skin health and the appearance of scarring, photoaging, fine lines, and wrinkles as well as stimulating hair growth.

PRP is usually derived from 10 to 20 mL of autologous blood that is centrifuged into three layers: red blood cells, platelet-poor plasma, and platelet-rich plasma. Depending on the system, the PRP may or may not be treated with thrombin to activate the platelets.



Less invasive, but more labor-intensive

"It is an autologous process, which is an advantage for people who don't like medications and might not want to use fillers in their skin," said session presenter Natasha Mesinkovska, MD, PhD, FAAD, associate professor of dermatology at the University of California Irvine School of Medicine and chief scientific officer for the National Alopecia Areata Foundation. "However, it is laborious to prepare and can be painful to administer."

And the effects are difficult to predict. The platelet concentration and growth factor profile in the final product depends largely on the whole blood from which each PRP dose is made. Platelet concentration and quality are highly variable, Dr. Ibrahim noted. Platelet integrity can vary by age, general health, recent injuries, medications, renal function, and other factors.

Single spin vs. double spin

"Whatever the brand, you're really looking at two approaches, single spin and double spin," Dr. Ibrahim said. "As the names suggest, single spin goes through the centrifuge once, double spin two times."

Single spin systems can yield PRP concentration anywhere from 1.5 to five times whole blood, he explained. Single spin systems require less whole blood, are easier to use, and less subject to human error.

Double spin systems can yield platelet concentrations up to nine times that of whole blood. Double spin systems require more whole blood, Dr. Ibrahim added, may include greater numbers of red blood cells, granulocytes, leukocytes, and other unwanted components, and are more subject to human error during the more complex production process.

Treatment response varies

"The same patient may not have the same response to the procedure from one time to the next," Dr. Mesinkovska told attendees. "That makes it very difficult to do studies and the variability of human blood makes it even more difficult to do well-controlled studies because every PRP treatment is unique."

There are no standards for PRP at this point, Dr. Mesinkovska cautioned attendees, and every system produces a unique product. She said she uses PRP primarily to stimulate hair growth and has found that patient selection is key to success.

"From studies and my own experience, I know that treating earlier in hair loss is better than later," Dr. Mesinkovska said. "If I have a patient who has alopecia universalis or major hair loss for a long time, I don't encourage them to try PRP. Yes, they will grow a little fuzz, but that may not make them happy. You have to manage patients' expectations."

PRODUCT SHOWCASE

Visit us at
BOOTH #869

TODAY'S HIGHLIGHTS

7 a.m. – 5 p.m.
Attendee registration
Location: East Level 0

9 a.m. – 5 p.m.
S024 - Gross and Microscopic Symposium
Location: 105

9 – 11 a.m.
F039 - Boards and Beyond
Location: 107A

F045 - Late-breaking Research: Clinical Studies/ Pediatric
Location: 253A

9 a.m. – 12 p.m.
S020 - Contact Dermatitis
Location: 258C

S021 - COVID-19 Dermatology and Vaccines
Location: Ballroom West

S022 - Residents and Fellows Symposium
Location: 162B

S023 - Diversity, Equity, and Inclusion
Location: 153C

S026 - Late-breaking Research: Clinical Trials
Location: 210A

9 a.m. – 12 p.m.
S027 - LGBTQ/SGM Health in Dermatology: Essentials and Updates
Location: 204A

10 a.m. – 5 p.m.
Exhibition Hall open

12 – 1 p.m.
Unopposed Exhibit Hall Hours

Officer Candidate Town Hall Meeting
Location: Exhibit Hall A, at entrance of North Lobby

1 – 3 p.m.
F055 - Late-breaking Research: Procedural Dermatology
Location: 107A

1 – 4 p.m.
S038 - Hot Topics
Location: Ballroom West

S041 - Skin of Color
Location: 206B

3:30 – 5:30 p.m.
F062 - Approach to Melanoma Diagnosis
Location: 257B

F067 - How Far Can We Get With Medical Imaging
Location: 109B

EXPERT ADVICE AND EDUCATION

Not an actual patient.

Model represents moderate-to-severe disease.

Adbry™
(tralokinumab-ldrm)
Injection 150 mg/mL

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MATTHEW ZIRWAS, MD
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BOSTON CONVENTION AND EXHIBITION CENTER

SATURDAY, MARCH 26 | 12:00 PM – 12:45 PM ET
PRODUCT SESSION ROOM #1 – EXHIBIT HALL

Explore the pathophysiology of atopic dermatitis and discuss a new treatment option for moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled.

The speaker is a consultant of LEO Pharma Inc. and was an investigator in the ECZTRA 1, 2, and 3 clinical trials.

This Product Session is a promotional activity and is not approved for continuing education credit.

The content of this session and opinions expressed by the presenter are those of the presenting company or presenters and do not represent an endorsement by, nor imply that the product has been evaluated or approved by the American Academy of Dermatology.

INDICATION

ADBRY™ (tralokinumab-ldrm) injection is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- ADBRY is contraindicated in patients who have known hypersensitivity to tralokinumab-ldrm or any excipients in ADBRY.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis and angioedema have occurred after administration of ADBRY. If a serious hypersensitivity reaction occurs, discontinue ADBRY immediately and initiate appropriate therapy.
- **Conjunctivitis and Keratitis:** Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received ADBRY. Conjunctivitis was the most frequently reported eye disorder. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Please see additional Important Safety Information and Brief Summary of the Prescribing Information on the following pages.

SCAN BELOW TO VISIT ADBRYHCP.COM

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START NOW

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Parasitic (Helminth) Infections:** Treat patients with pre-existing helminth infections before initiating treatment with ADBRY. If patients become infected while receiving ADBRY and do not respond to antihelminth treatment, discontinue treatment with ADBRY until the infection resolves.
- **Risk of Infection with Live Vaccines:** ADBRY may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to initiating therapy with ADBRY, complete all age appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with ADBRY. Limited data are available regarding coadministration of ADBRY with non-live vaccines.

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥1%) are upper respiratory infections, conjunctivitis, injection site reactions, and eosinophilia.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are limited data from the use of ADBRY in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, ADBRY may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of tralokinumab-ldrm in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is present in breast milk. The effects of local gastrointestinal exposure and limited systemic exposure to ADBRY on the breastfed infant are unknown.
- **Pediatric Use:** The safety and effectiveness of ADBRY have not been established in pediatric patients.

Please see Brief Summary of the Prescribing Information on the next page.

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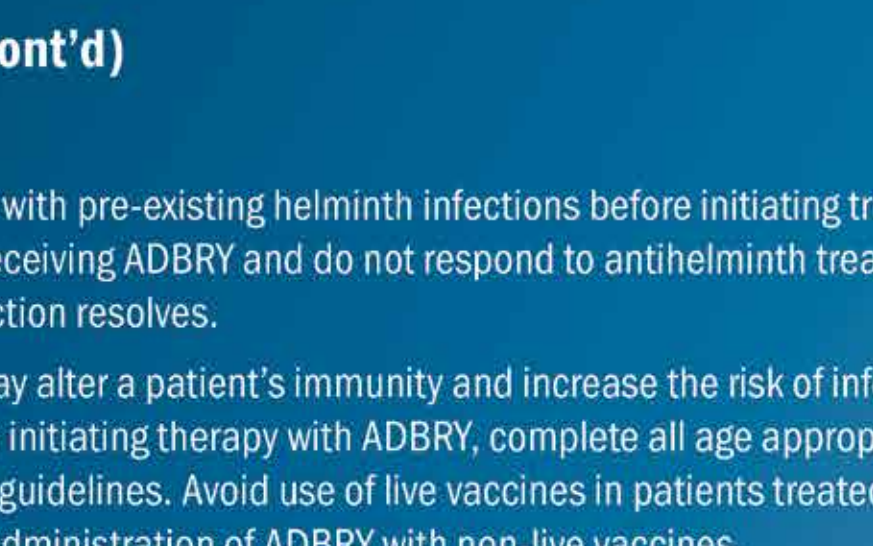

Adbry™
(tralokinumab-ldrm)
Injection 150 mg/mL

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MAT-55058 February 2022

ADBRY™ (tralokinumab-ldrm) injection, for subcutaneous use

Initial U.S. Approval 2021

Brief Summary of Prescribing Information

This Brief Summary does not include all the information needed to use ADBRY safely and effectively. Please see Full Prescribing Information.

Rx Only

INDICATIONS AND USAGE
ADBRY is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

CONTRAINDICATIONS
ADBRY is contraindicated in patients who have known hypersensitivity to tralokinumab-ldrm or any excipients in ADBRY.

WARNINGS AND PRECAUTIONS
Hypersensitivity
Hypersensitivity reactions including anaphylaxis and angioedema, have been reported with use of ADBRY.

If a serious hypersensitivity reaction occurs, discontinue ADBRY immediately and initiate appropriate therapy.

Conjunctivitis and Keratitis
Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received ADBRY. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period.

Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Parasitic (Helminth) Infections
Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if ADBRY will influence the immune response against helminth infections by inhibiting IL-13 signaling.

Treat patients with pre-existing helminth infections before initiating treatment with ADBRY. If patients become infected while receiving ADBRY and do not respond to antihelminth treatment, discontinue treatment with ADBRY until the infection resolves.

Risk of Infection with Live Vaccines
ADBRY may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to initiating therapy with ADBRY, complete all age appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with ADBRY. Limited data are available regarding coadministration of ADBRY with non-live vaccines.

ADVERSE REACTIONS
The following adverse reactions are discussed in greater detail elsewhere in the labeling:
- Hypersensitivity
- Conjunctivitis and Keratitis

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.

The safety of ADBRY was evaluated in a pool of 5 randomized, double-blind, placebo-controlled trials in subjects with moderate-to-severe atopic dermatitis including three phase 3 Eczema Tralokinumab trials (ECZTRA 1, ECZTRA 2, and ECZTRA 3), a dose-finding trial, and a vaccine response trial. The safety population had a mean age of 37 years; 43% of subjects were female, 67% were White, 21% were Asian, and 9% were Black. In terms of co-morbid conditions, 39% of the subjects had asthma, 49% had hay fever, 36% had food allergy, and 21% had allergic conjunctivitis at baseline.

In these 5 atopic dermatitis trials, 1964 subjects were treated with subcutaneous injections of ADBRY, with or without concomitant topical corticosteroids (TCS). A total of 807 subjects were treated with ADBRY for at least 1 year.

ECZTRA 1 and ECZTRA 2 compared the safety of ADBRY monotherapy to placebo through Week 52. ECZTRA 3 compared the safety of ADBRY + TCS to placebo + TCS through Week 32.

Weeks 0 to 16 (ECZTRA 1, ECZTRA 2, and ECZTRA 3):
Table 1 summarizes the adverse reactions identified in the pool of 3 trials (ECZTRA 1, ECZTRA 2, and ECZTRA 3) and that occurred at a rate of at least 1% in the ADBRY 300 mg every other week monotherapy group, and in the ADBRY 300 mg every other week + TCS study, all at a higher rate than placebo during the first 16 weeks of treatment.

Table 1: Adverse Reactions Occurring in ≥1% of the ADBRY Monotherapy Group or the ADBRY + TCS Group in the Atopic Dermatitis Trials through Week 16

Adverse Reaction	ADBRY Monotherapy[a]		ADBRY + TCS[b]	
	ADBRY 300 mg Q2W[c] N=1180 n (%)	PLACEBO N=388 n (%)	ADBRY 300 mg Q2W[c] + TCS N=243 n (%)	PLACEBO + TCS N=123 n (%)
Upper respiratory tract infections[d]	281(23.8)	79 (20.4)	73 (30.0)	19 (15.4)
Conjunctivitis[f]	88 (7.5)	12 (3.1)	33 (13.6)	6 (4.9)
Injection site reactions[e]	87 (7.4)	16 (4.1)	27 (11.1)	1 (0.8)
Eosinophilia[g]	17 (1.4)	2 (0.5)	3 (1.2)	0

[a]Pooled analysis of ECZTRA 1 and ECZTRA 2.
[b]Analysis of ECZTRA 3 where subjects were on background TCS therapy.
[c]ADBRY 600 mg at Week 0, followed by 300 mg every other week.
[d]Upper respiratory tract infections cluster includes upper respiratory tract infection, viral upper respiratory tract infection, pharyngitis, and nasopharyngitis; mainly reported as common cold.
[e]Injection site reactions cluster includes pain, erythema, and swelling.
[f]Conjunctivitis cluster includes conjunctivitis and allergic conjunctivitis.
[g]Eosinophilia cluster includes eosinophilia and eosinophil count increased.

In the monotherapy trials (ECZTRA 1 and ECZTRA 2) through Week 16, the proportion of subjects who discontinued treatment due to adverse reactions was 0.7% in the ADBRY 300 mg every other week group and 0% of the placebo group. In the concomitant TCS trial (ECZTRA 3) through Week 16, the proportion of subjects who discontinued treatment due to adverse reactions was 0.8% in the ADBRY 300 mg every other week + TCS group and 0% of the placebo + TCS group. The most common adverse reactions leading to discontinuation in the ADBRY group compared to the placebo group were injection site reaction (0.3% v. 0) and eosinophilia (0.3% v. 0) in ECZTRA 1 and ECZTRA 2; and injection site reaction (0.4% v. 0) and conjunctivitis (0.4% v. 0) in ECZTRA 3.

Safety Weeks 16-52 (ECZTRA 1 and ECZTRA 2) and Weeks 16-32 (ECZTRA 3): The safety profile of ADBRY 300 mg every other week with or without TCS during maintenance treatment was consistent with that in the initial 16-week treatment period. In addition, the frequency of adverse reactions with ADBRY 300 mg every other week and every 4 weeks in ECZTRA 1 and ECZTRA 2 was 44% and 34%, respectively, and 43% and 26% with ADBRY 300 mg + TCS every other week and every 4 weeks in ECZTRA 3, respectively.

Specific Adverse Reactions
Conjunctivitis and Keratitis
Conjunctivitis, including allergic conjunctivitis, was reported in 7.5% of subjects treated with ADBRY 300 mg every other week (29 events per 100 subject-years of exposure) and in 3.1% of subjects treated with placebo (12 events per 100 subject-years of exposure) in the initial treatment period of up to 16 weeks in the pool of 5 trials. In the ADBRY group, 126 subjects reported 145 events of conjunctivitis, with 114 events resolved at the end of initial treatment period. Conjunctivitis led to discontinuation of treatment in 2 subjects.

During the maintenance treatment period of the monotherapy trials (ECZTRA 1 and ECZTRA 2) from 16 to 52 weeks, conjunctivitis was reported in 8.9% of subjects treated with ADBRY 300 mg every other week (20 events per 100 subject-years of exposure) and in 6.3% of subjects treated with ADBRY 300 mg every 4 weeks (14 events per 100 subject-years of exposure) compared to 7.7% of subjects treated with ADBRY 300 mg every other week in the initial treatment period (30 events per 100 subject-years of exposure). Conjunctivitis (including no serious events, 1 severe event, and 1 event that led to discontinuation) was reported in 24 subjects in the combined (every other week and every 4 weeks) ADBRY groups. A similar pattern was seen during the continuation treatment period of an additional 16 weeks in the ADBRY combination ECZTRA 3.

Keratitis (including keratoconjunctivitis) was reported in 0.5% of subjects treated with ADBRY and 0% treated with placebo during the initial treatment period of up to 16 weeks in the pool of 5 trials. Keratitis (including 1 ulcerative keratitis) was reported in 0.2% of subjects treated with ADBRY (0.9 events per 100 subject-years of exposure) and 0.2% of subjects treated with placebo (0.6 events per 100 subject-years of exposure). Keratoconjunctivitis (including 1 atopic keratoconjunctivitis) was reported in 0.3% of subjects treated with ADBRY (1.2 events per 100 subject-years of exposure), and in no subjects treated with placebo. In the ADBRY group, 9 subjects reported 10 events of keratitis or keratoconjunctivitis, with 5 events resolved during the trial following the initial treatment period. None of the events were serious or led to treatment discontinuation.

During the maintenance treatment period of the monotherapy trials (ECZTRA 1 and ECZTRA 2) from 16 to 52 weeks in the ADBRY 300 mg every other week group, keratitis was reported in 1 (0.6%) subject (ulcerative, severe, resolved after discontinuation) at an exposure-adjusted event rate of 1.2 per 100 subject-years, and keratoconjunctivitis (not serious or severe, resolved, not led to discontinuation) was reported in 3 (1.9%) subjects (3.6 events per 100 subject-years of exposure). No events of keratitis or keratoconjunctivitis was reported in ADBRY every 4 weeks or placebo groups, compared to keratitis event rate of 2 per 100 subject-years for ADBRY 300 mg every other week in the initial treatment period.

In the continuation treatment period of ECZTRA 3 (from 16 to 32 weeks), there were no additional events of keratitis reported for subjects randomized to ADBRY 300 mg + TCS.

Eosinophil Counts
ADBRY-treated subjects had a greater mean initial increase from baseline in eosinophil count compared to subjects treated with placebo. The mean and median increases in blood eosinophils from baseline to Week 4 were 190 and 100 cells/mcL, respectively. The increase in the ADBRY-treated subjects declined to baseline level with continued treatment. Eosinophilia (> 5000 cells/mcL) in the initial treatment period of up to 16 weeks was reported in 1.2% in the ADBRY-treated subjects and 0.3% in the placebo-treated subjects. The safety profile for subjects with eosinophilia was comparable to the safety profile for all subjects included in the pool of 5 atopic dermatitis trials.

Immunogenicity
As with all therapeutic proteins, there is a potential for immunogenicity with ADBRY. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other tralokinumab products may be misleading.

In ECZTRA 1, ECZTRA 2, and ECZTRA 3, and the vaccine-response trial, the incidence of Anti-Drug-Antibodies (ADA) during the initial 16-week treatment period was 1.4% for subjects treated with ADBRY 300 mg every other week and in 1.3% for subjects treated with placebo; neutralizing antibodies were seen in 0.1% of subjects treated with ADBRY and 0.2% of subjects treated with placebo.

Across all trial periods, the ADA incidence for subjects who received ADBRY was 4.6%; 0.9% had persistent ADA and 1.0% had neutralizing antibodies.

No clinically meaningful differences in the pharmacokinetics, safety, or efficacy of tralokinumab-ldrm were observed in patients who tested positive for anti-tralokinumab-ldrm antibody (including neutralizing antibodies).

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
There are limited data from the use of ADBRY in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, ADBRY may be transmitted from the mother to the developing fetus.

In an enhanced pre- and post-natal developmental study, no adverse developmental effects were observed in offspring born to pregnant monkeys after intravenous administration of tralokinumab-ldrm during organogenesis through parturition at doses up to 10 times the maximum recommended human dose (MRHD).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data
Animal Data
In a pre- and post-natal development study, intravenous doses up to 100 mg/kg tralokinumab-ldrm were administered to pregnant cynomolgus monkeys once every week from gestation day 20 to parturition. No maternal or developmental toxicity was observed at doses up to 100 mg/kg/week (10 times the MRHD on a mg/kg basis of 10 mg/kg/week).

In an enhanced pre- and post-natal development study, intravenous doses up to 100 mg/kg tralokinumab-ldrm (10 times the MRHD on a mg/kg basis of 10 mg/kg/week) were administered to pregnant cynomolgus monkeys once every week from the beginning of organogenesis to parturition. No treatment-related adverse effects on embryofetal toxicity or malformations, or on morphological, functional, or immunological development were observed in the infants from birth through 6 months of age.

Lactation
Risk Summary
There are no data on the presence of tralokinumab-ldrm in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is present in breast milk. The effects of local gastrointestinal exposure and limited systemic exposure to ADBRY on the breastfed infant are unknown. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for ADBRY and any potential adverse effects on the breastfed child from ADBRY or from the underlying maternal condition.

Pediatric Use
The safety and effectiveness of ADBRY have not been established in pediatric patients.

Geriatric Use
Of the 1605 subjects exposed to ADBRY in 5 atopic dermatitis trials in the initial treatment period of up to 16 weeks, 77 subjects were 65 years or older. Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE
There is no specific treatment for ADBRY overdose. In the event of overdosage, contact Poison Control (1-800-222-1222) for latest recommendations and monitor the patient for any signs or symptoms of adverse reactions and institute appropriate symptomatic treatment immediately.

PATIENT COUNSELING INFORMATION
Advise the patients to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Administration Instructions
Instruct patients or caregivers:
- to perform the first self-injection under the supervision and guidance of a qualified healthcare provider for proper training in subcutaneous injection technique
- to inject the full dose of ADBRY
- to follow sharps disposal recommendations *[see Instructions for Use]*

Hypersensitivity
Advise patients to discontinue ADBRY and to seek immediate medical attention if they experience any symptoms of systemic hypersensitivity reactions.

Conjunctivitis and Keratitis
Advise patients to consult their healthcare provider if new onset or worsening eye symptoms develop.

Risk of Infection with Live Vaccines
Advise patients that ADBRY may increase the risk of infection following administration of live vaccines and that vaccination with live vaccines is not recommended during ADBRY treatment. Instruct patients to inform the healthcare provider that they are taking ADBRY prior to a potential vaccination.

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AAD/NPF Guidelines: Managing psoriasis


Mary E. Horner, MD, FAAD


Dario Kivelevitch, MD, FAAD


April W. Armstrong, MD, MPH, FAAD


Alan Menter, MD, FAAD

Psoriasis isn't just a skin condition. It's a systemic immune-mediated disease that can impact a patients' quality of life and their risk of comorbidities. To improve patient care, Friday's **S001 –AAD/NPF Guidelines** focused on four important areas of psoriasis management.

Reclassifying psoriasis severity

To categorize psoriasis severity and prescribe the most appropriate treatment, dermatologists often rely on body surface area to calculate a psoriasis area and severity index (PASI) score. But body surface area can be a poor indicator of psoriasis severity in patients with special site involvement.

"Special areas are commonly involved in psoriasis patients, including the scalp, palms, soles, nails, and genitals, which can create more burden in terms of quality of life and psychosocial issues," said Mary E. Horner, MD, FAAD, with Dermatology Consultants of Sacramento, California. "If you have a patient with body surface area of 1%, but it's on your palms, it's going to be painful. If it's on your face, how might that affect your relationships and your career choices?" Dr. Horner presented evidence that quality of life — the Dermatology Life Quality Index — may be a better indicator of psoriasis severity.

Traditional definitions of moderate and severe psoriasis, based on body surface area, are inadequate to determine the need for systemic/biologic therapy, Dr. Horner said. Special areas of involvement should upgrade severity irrespective of body surface area involvement. "Adhering to BSA rules creates undertreatment, based on true patient needs," Dr. Horner said. "We need to ask our patients: 'How is your psoriasis affecting your life?'"

Detecting psoriatic arthritis earlier

About 30% of patients with psoriasis will develop psoriatic arthritis. Psoriasis usually precedes the onset of psoriatic arthritis by an average of five to 10 years in approximately 80% of patients. "There are ways we can help our patients early on in the game," said Dario Kivelevitch, MD, FAAD, dermatology residency program director, Baylor Scott & White Health in Dallas. To identify psoriatic arthritis, Dr. Kivelevitch employs the Psoriasis Epidemiology Screening Tool, which asks patients five questions. "Early detection and treatment can prevent joint destruction. Dermatologists should screen psoriasis patients for psoriatic arthritis at every visit," Dr. Kivelevitch said. He presented treatment options based on the 2018 ACR/NPF Guidelines for the Treatment of Psoriatic Arthritis, of which only 6% are strong recommendations. "We need more evidence to develop guidelines for better management," he said.

Comparing biologic medication

Which biologic drug is the best option for your psoriasis patient? Network meta-analysis can help you decide, said presenter April W. Armstrong, MD, MPH, FAAD, associate dean of clinical research at the Keck School of Medicine at the University of Southern California in Los Angeles. Network meta-analyses compare multiple treatments simultaneously in a single analysis, combine direct and indirect evidence, and assess the comparative effectiveness of different treatments. Dr. Armstrong discussed the utility of network meta-analysis for comparing the efficacy and safety of the 11 FDA-approved biologic medication for psoriasis, using selected published network meta-analysis in psoriasis since 2020. When evaluating the results, it's important to ask: What outcomes are being measured and in what specific time period? Your conclusion may be different if you look at an early versus later time period, Dr. Armstrong cautioned.

Cardiovascular comorbidities

Alan Menter, MD, FAAD, a leader in guidelines development and our understanding of psoriasis and psoriatic arthritis, wrapped up the session with a discussion of the relationship between psoriasis and cardiovascular comorbidities.

"Psoriasis is not a skin disease. It's a systemic immune-mediating disease, and systemic inflammation is critical. Systemic inflammation is also part of cardiovascular disease." Dr. Menter urged dermatologists to screen for cardiovascular risk factors in their patients with psoriasis and manage them according to national guidelines.

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Window to COVID-related clues

Why do people respond differently to the COVID-19 virus — and the vaccine? Do dermatologists have a window into clues?

Esther Ellen Freeman, MD, PhD, FAAD, principal investigator for the COVID-19 Dermatology Registry, a collaboration with the AAD and International League of Dermatological Societies, and an associate professor of dermatology at Harvard Medical School

Similar virus, different people

"The virus presents very differently in different people," Dr. Freeman said. "It's the same virus. The difference is in how a patient's immune system responds to it."

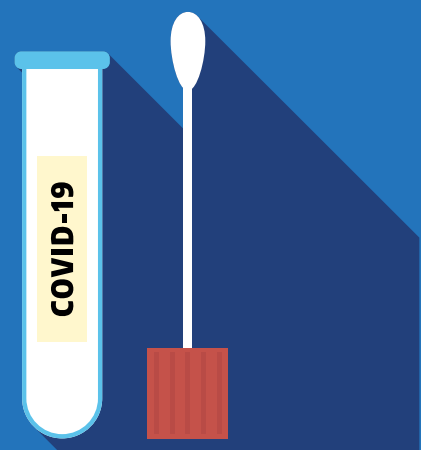
Dermatologic clues are often related to COVID variants as well, Dr. Freeman said. As such, she encourages dermatologists to use these clues, particularly since many see their patients regularly and are a trusted resource.

Skin manifestations of the virus and the vaccine can tell us a lot, according to Esther Ellen Freeman, MD, PhD, FAAD, principal investigator for the COVID-19 Dermatology Registry, a collaboration with the AAD and International League of Dermatological Societies, and an associate professor of dermatology at Harvard Medical School. Dr. Freeman will lead this morning's session session, **S021 – COVID-19 Dermatology and Vaccines**, which looks at everything from COVID skin manifestations to the dermatologist's influence in educating patients about the vaccine.

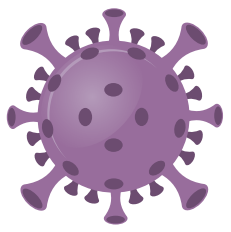
"There is a wide spectrum of COVID-19 skin manifestations. Over 30 different skin manifestations have been identified to date, and these often serve as clues to how our immune system is responding to COVID," she said.

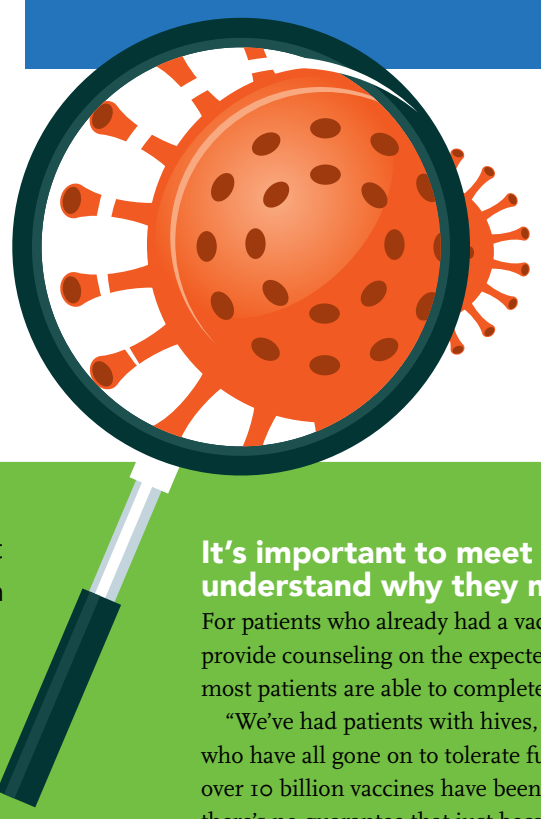
According to Dr. Freeman, mild COVID symptoms often accompany milder skin manifestations, such as pernio chilblains, sometimes referred to as "COVID toes." Patients with moderate symptoms of COVID might present with hives or a vesicular eruption. Severe COVID symptoms, in which a patient is hospitalized and on a ventilator, may be accompanied by retiform purpura, signifying more serious coagulation issues.

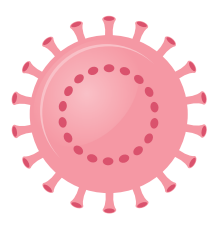
"When you see a new or unexplained rash, consider COVID-19 if you don't have another answer. The threshold to do a COVID test in your office should be low. In the beginning, it was hard to access those tests, but now we can." We know that in COVID cases where patients experience a rash, up to 20% of them may have a rash as either the first, or the only symptom. For example, new-onset hives without other explanation can be the first symptom of COVID-19."

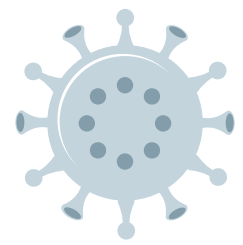


S021 – COVID-19 Dermatology and Vaccines
Saturday, March 26 | 9 a.m. – 12 p.m.
Room: Ballroom West

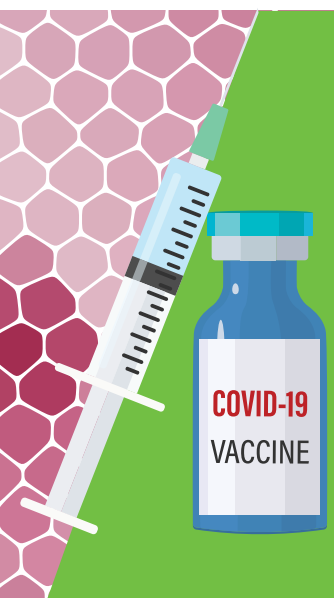








Vaccination progression



Because vaccine reactions can last longer in some cases, Dr. Freeman emphasizes dermatologists play an important role in reducing the transmission and severity of COVID-19 through vaccination. The AAD/ILDS COVID-19 Dermatology Registry is still accepting cases at **aad.org/covidregistry.**

It's important to meet your patient where they are and understand why they may be experiencing vaccine hesitancy.

For patients who already had a vaccine reaction to an earlier dose, dermatologists can provide counseling on the expected course with future vaccinations. Dr. Freeman said most patients are able to complete their vaccine series.

"We've had patients with hives, patients with blisters, patients with morbilliform rashes, who have all gone on to tolerate further vaccine doses," Dr. Freeman said. "Worldwide, over 10 billion vaccines have been given. Vaccines are incredibly safe and effective, and there's no guarantee that just because you had a reaction with the first vaccine dose that you will have the same or worse with the second or the booster. In fact, a reaction occurs after the second dose less than 50% of the time. And the reaction usually disappears on its own after two weeks."

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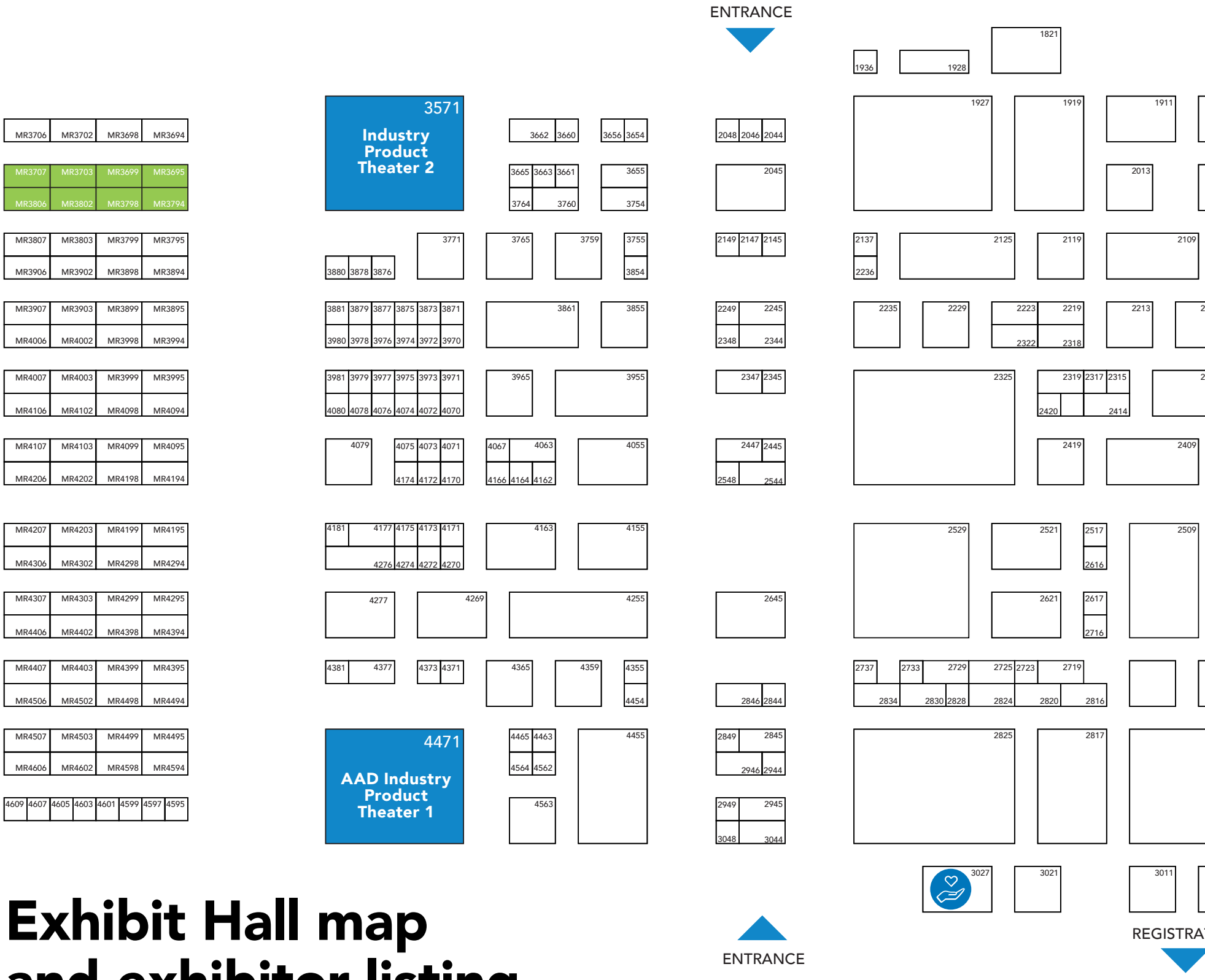

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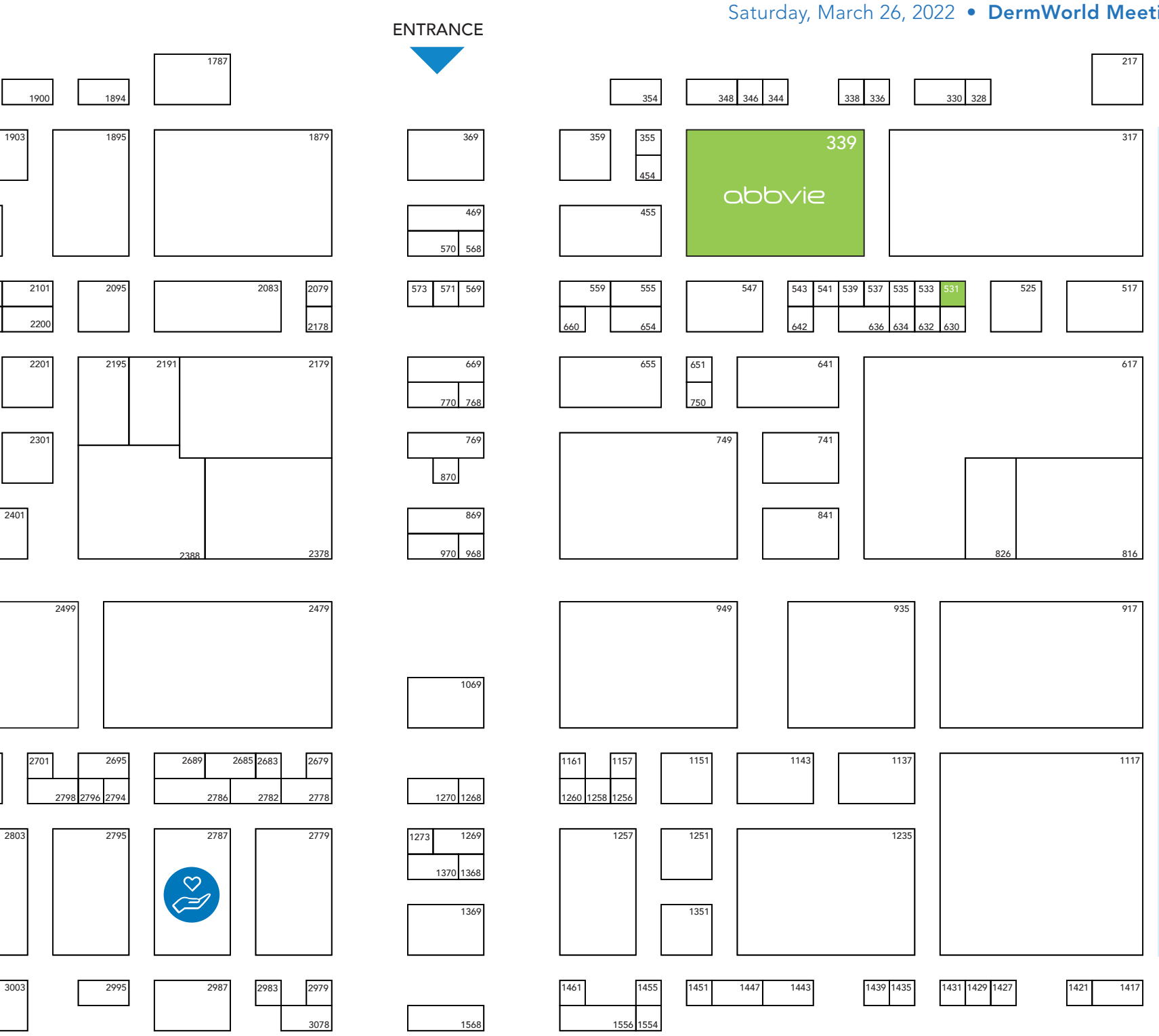

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8:30 a.m. – 5 p.m.

Sunday, March 27
8:30 a.m. – 2 p.m.

Exhibit Hall:
Booth 001
Booth 002

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003

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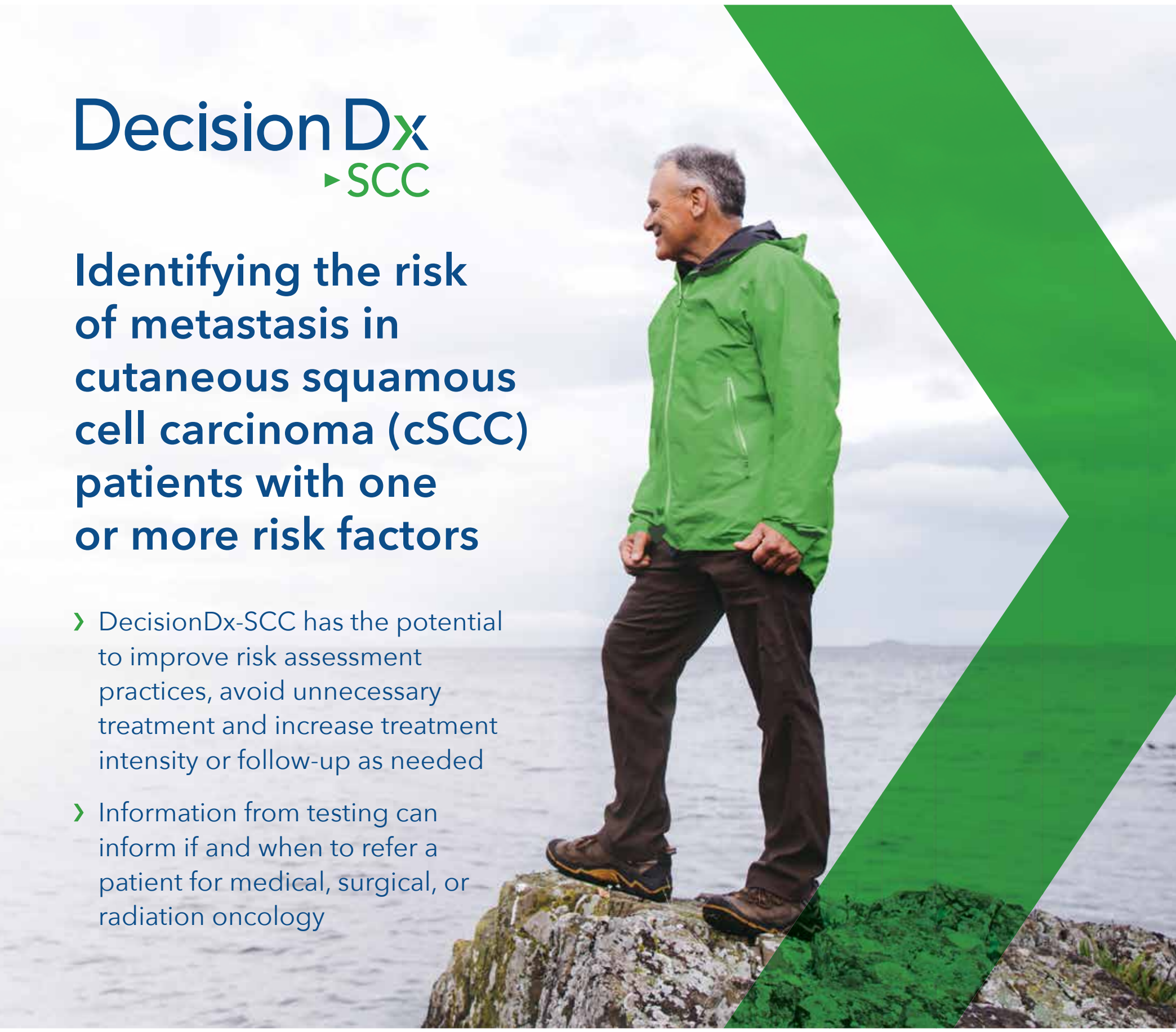

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Experts urge competence treating diseases in all skin colors

Even though nearly half of the U.S. population, and most of the global population, has non-Caucasian skin, physicians still often encounter clinical images that feature only light-colored skin. Treating disease in a diverse range of skin colors requires knowledge and skill. Quite simply, different skin colors react differently to the same treatment. These issues will be discussed in depth during **S041 – Skin of Color**, happening today in Room 206B, from 1-4 p.m.

Unmasking facial hyperpigmentation
Amit G. Pandya, MD, FAAD, clinical professor of dermatology at The University of Texas Southwestern Medical Center and practicing dermatologist at the Palo Alto Foundation Medical Group in Sunnyvale, California

Management of cicatricial alopecia
Amy J. McMichael, MD, FAAD, professor and chair of dermatology at Atrium Wake Forest Baptist Medical Center

Update on hidradenitis suppurativa
Iltefat H. Hamzavi, MD, FAAD, lead at the Multicultural Dermatology Clinic, and director of the Hidradenitis Suppurativa Clinic at Henry Ford Hospital

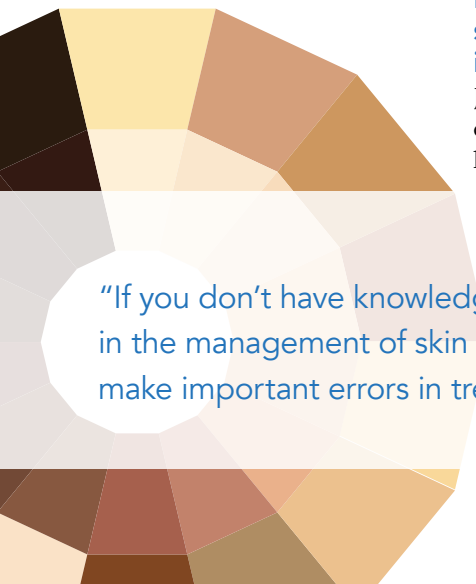
New discoveries in keloids
Donald A. Glass II, MD, PhD, FAAD, associate professor of dermatology at The University of Texas Southwestern Medical Center

What's new in vitiligo
John E. Harris, MD, PhD, FAAD, professor and chair of dermatology, founding director of the Vitiligo Clinic and Research Center and the Autoimmune Therapeutics Institute at University of Massachusetts Chan Medical School

Diseases can present differently

"For example, if you do a chemical peel on someone with very light skin, they usually tolerate it well, recover, and have improvement in their appearance. But if you do the same peel on someone with darker skin, they may have profound hyperpigmentation or hypopigmentation and those changes can persist for weeks or months. If you don't have knowledge or experience in the management of skin of color, you can make important errors in treatment," said Amit G. Pandya, MD, FAAD, clinical professor of dermatology at The University of Texas Southwestern Medical Center and practicing dermatologist at the Palo Alto Foundation Medical Group in Sunnyvale, California. Dr. Pandya is among the speakers at today's session.

Black patients are more likely to have central centrifugal cicatricial alopecia (CCCA), which manifests as scarring over the vertex scalp and expands outward circumferentially, than women with lighter skin. Black women are also more likely than women of other skin colors to develop traction alopecia, which begins as a nonscarring hair loss at the frontal scalp and progresses to scarring alopecia at the lateral sides of the scalp. Women of European descent more often have frontal fibrosing alopecia and typical lichen planopilaris.



Early detection

"The best practice in early diagnosis of cicatricial alopecia is to recognize mild disease early with trichoscopy and/or biopsy," said Amy McMichael, MD, FAAD, professor and chair of dermatology at Atrium Wake Forest Baptist Medical Center. "When early disease is found, it is important to treat with anti-inflammatory topicals, injection, and systemic treatments long term. In the post-inflammatory stages, topical and oral minoxidil can be used for follicular rescue," she said.

"There is a real need for dermatologists to be competent in recognizing how skin disease appears in all skin colors and how to approach the cultural skin and hair practices of all ethnicities," Dr. McMichael added.

Hidradenitis suppurativa common in Black Americans

Just as skin cancer disproportionately affects lighter skin types, hidradenitis suppurativa (HS) is more common in individuals of African ancestry. Black Americans have three times the prevalence of HS compared to the general population, said Iltefat Hamzavi, MD, FAAD, lead at the Multicultural Dermatology Clinic, and director of the Hidradenitis Suppurativa Clinic at Henry Ford Hospital.

"It takes about seven years for the typical patient to get an HS diagnosis, so recognizing and treating it early can dramatically improve care," he added. "A dermatologist can diagnose HS in 10 seconds with just two questions."

Treatment has improved dramatically in recent years, including antibiotics, biologics, and surgery. Recent work suggests that Black patients with HS may be a subpopulation at lower risk of developing keloids following surgery, Dr. Hamzavi said.

"HS patients do not take longer than the typical dermatology patient," he said. "You just have to know what to do and to connect them with HS support groups. HS carries so much psychological trauma that support groups are critical for this community, online and in person."

> "If you don't have knowledge or experience in the management of skin of color, you can make important errors in treatment."
> – Dr. Pandya

Stay cognizant of keloids

Keloids are not more common in skin of color but can occur in all races and ethnicities. On darker skin, the plaques and papules are skin-colored to hyperpigmented.

"You see keloids on individuals of European ancestry, but they don't tend to be as protuberant as on darker skin," said Donald Glass II, MD, PhD, FAAD, associate professor of dermatology at The University of Texas Southwestern Medical Center. "Dermatologists should be cognizant of keloids occurring across all skin tones. With the mix of ancestries in the United States, a Caucasian person may be able to develop keloids similar to a Black individual."

Accurate diagnosis can be lifesaving. Keloids and dermatofibrosarcoma protuberans (DFSP) share common surface features, although DFSP tends to spread more than keloids.

"If you have what looks like an atypical keloid, if you palpate around the margin and find areas of induration, be concerned for DFSP," Dr. Glass said. "Keloids don't tend to send out roots underneath normal-appearing skin and DFSP can do that. Don't be afraid to do a biopsy — you want to be sure you're not missing something worse."

Complications of vitiligo

Today's session will also include in-depth discussion of vitiligo.

"About 1.5% of the population gets vitiligo regardless of skin type," said John E. Harris, MD, PhD, FAAD, professor and chair of dermatology, founding director of the Vitiligo Clinic and Research Center and the Autoimmune Therapeutics Institute at University of Massachusetts Chan Medical School.

"Light skin has the complication of darkening in summer so you see the vitiligo that you can't see in winter. A lot of people with light skin and vitiligo fear the sun because the vitiligo will 'relapse' in summer. I'm hoping that dermatologists will stop telling patients there's no treatment; nothing to be done. That's far from the truth."

There is no cure for vitiligo, he said. But UVB treatment can dramatically reduce the severity of vitiligo in both light and dark skin and ease the psychosocial burden it can bring.

"Too many dermatologists are not familiar with the differences in skin of color compared to lighter skin," Dr. Harris said. "And those differences can be critical to diagnosis and treatment. Even those dermatologists who practice in areas where they don't see a lot of skin of color need to be prepared to take care of all their patients." ●

S041 – Skin of Color
Saturday, March 26 | 1 – 4 p.m.
Room: 206B

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Lighting up new applications in pediatric dermatology

Lisa M. Arkin, MD, FAAD, associate professor and director of pediatric dermatology at the University of Wisconsin School of Medicine and Public Health

Selective thermolysis and other light-based techniques are familiar approaches to treating port wine birthmarks and other vascular anomalies. Adults who are naive to treatment respond even less effectively to light-based techniques than children. In fact, early treatment (before 1 year of age) has been shown to significantly improve outcomes with laser. There's a significant gap in knowledge about the pathobiology of these birthmarks, why they progress over time, and how to optimally treat regardless of age. We need to close this gap to move from bench to bedside; this will improve the care of all patients across the age spectrum.

There is a clear need for greater collaboration between laser surgeons and pediatric dermatologists to identify best practices for laser-tissue interactions in children, said Lisa M. Arkin, MD, FAAD, associate professor and director of pediatric dermatology at the University of Wisconsin School of Medicine and Public Health, and the session moderator for **U044 – Uses for Laser & Light-Based Devices in Pediatric Patients**. The session, co-moderated by Kristen M. Kelly, MD, FAAD, dermatology chair at the University of California, Irvine, is designed to encourage this collaborative dialogue about treating vascular anomalies in children and some of the new approaches that could enhance treatment outcomes.

Selective absorption

"The lasers used in dermatology affect specific light-absorbing targets based on selective thermolysis, the selective absorption of light energy by specific chromophore targets, most often hemoglobin, melanin, or water," Dr. Arkin said. "We are essentially performing microsurgery and sparing the surrounding tissue. The energy delivered to the target chromophore, hemoglobin in the case of vascular birthmarks, produces a specific reaction in the skin, which is your clinical endpoint and optimally leads to clearance of the vasculature."

Age-appropriate treatment

Age-specific concerns can guide optimal dosimetry and settings for treatment. Further, they may instruct on the potential for non-invasive imaging to guide laser treatment and pharmacologic adjuvant treatment to block specific molecular pathways responsible for these vascular anomalies.

Photocoagulation

Not every port wine birthmark responds optimally. Laser treatment settings are sometimes ineffective. Photocoagulation may be incomplete because the vessel is too dilated or too deep. Additionally, laser treatment does not alter the genetic mutations leading to most vascular anomalies.

"Incomplete photocoagulation is generally ineffective," she said. "We know you need purpura for optimal results, but it doesn't work in every patient."

Port wine stains are caused by mosaic mutations of specific genes that produce cell cycle activation, although the downstream expression pathways are still poorly understood. Because we think the most common mutation in port wine stains, GNAQR183, is harbored within the endothelial cell, effective laser treatment could theoretically remove the genetic change through vascular ablation. However, we undoubtedly leave some vessels that are too deep or too dilated, and some may regrow over time. Therefore, laser is an imperfect treatment and underscores why we need targeted medical therapies, which could be combined with light.

"We know that many port wine birthmarks develop progression over time, including the development of stigmatizing soft tissue overgrowth and vascular blebs, which can bleed," she said.

"We need to leverage the knowledge regarding genomics, which might include novel imaging to optimize our laser parameters. If we can quantitate the vessel depth and diameter, we may be able to tweak our laser parameters. The goal is to look at the patient, be able to predict their mutation based on genotype-phenotype mutations, and prescribe a topical medication to help optimize clearance when combined with laser."

New OCT technology

Optical coherence tomography (OCT) shows early promise in evaluating the vasculature in vascular birthmarks, she said. There are promising correlations between genotype and phenotype in vascular patterning using OCT, but additional studies are needed to demonstrate clinical utility. ●

UPCOMING SESSION
U044 – Uses for Laser & Light-Based Devices in Pediatric Patients
Saturday, Mar. 26 | 4:30 – 5:30 p.m.
Room: 160A

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American Academy of Dermatology |Association
9500 W. Bryn Mawr Ave.
Rosemont, IL 60018-5216
Phone (847) 330-0230;
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