AAD
DermWorld meeting news
SUNDAY. MARCH 27, 2022
A Publication of the American Academy of Dermatology | Association

Sunday's Plenary lineup
8 a.m.–12 p.m.
Ballroom East/West

David M. Ozog, MD, FAAD
Chair's Welcome

Amit G. Pandya, MD, FAAD
Clarence S. Livingood, MD Memorial Award and Lectureship

Kenneth J. Tomecki, MD, FAAD
President's Address

Steven Kenneth Shama, MD, MPH, FAAD
Derm Tales: What I Learned About The Most Powerful Form of Oral Punctuation... The Pause...and How It Changed My Life

Alain H. Rook, MD, FAAD
Eugene J. Van Scott Award for Innovative Therapy of the Skin and Phillip Frost Leadership Lecture

Mark D. Kaufmann, MD, FAAD
President-Elect's Address

Robert Daze, DO
DermTales: A Summer to Remember

Otis Brawley, MD
Lila and Murray Gruber Memorial Cancer Research Award and Lectureship

Keith Choate, MD, PhD, FAAD
Marion B. Sulzberger, MD, Memorial Award and Lectureship

Susan C. Taylor, MD, FAAD
John Kenney, MD, Memorial Award and Lectureship

Doris Kearns Goodwin
Keynote speaker

Watch for coverage of the Plenary on Monday, March 28 in *DermWorld Meeting News* e-daily.

Dermatology plays a prominent role on the COVID-19 world stage

Skin, hair, and nail disorders continue to present as major manifestations of COVID-19. "About 10% of people with COVID-19 will have skin manifestations (accompanied by other symptoms) and about 20% will have only skin manifestations. We truly are on the front line," said Esther Ellen Freeman, MD, PhD, FAAD, director of global health dermatology at Massachusetts General Hospital and principal investigator of the COVID-19 Dermatology Registry, who moderated Saturday's S021 – COVID-19 Dermatology and Vaccines. The presentation featured a comprehensive overview of key dermatology-related conditions associated with COVID-19, anchored by fellow expert speakers from the AAD Ad Hoc Task Force on COVID-19.

COVID-19, psoriasis, and biologics

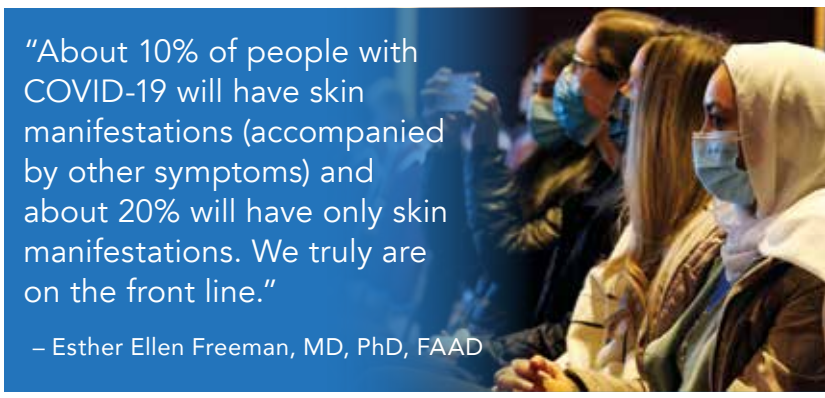
Are patients with psoriasis who are treated with tumor necrosis factor inhibitors (TNFi) or IL-17 inhibitors at increased risk of adverse COVID-19-related outcomes? These patients do not have an increased rate of COVID-19 hospitalization or mortality, compared with patients who did not receive TNFi exposure, said April W. Armstrong, MD, MPH, FAAD, associate dean of research and professor of dermatology at the University of Southern California. Dr. Armstrong presented real-world data on COVID-19 infections and vaccine considerations.

What about COVID-19 vaccine recommendations for psoriasis patients? According to CDC guidelines, patients 12 and older who are severely immunocompromised should receive four doses of an mRNA vaccine and one booster dose five months after the primary series.

"Most psoriasis patients are not severely immunocompromised and aren't required to have the third dose, but we do recommend a booster," Dr. Armstrong said. If patients are scheduled to get the COVID-19 vaccine the same week as their biologic dose, consider delaying the biologic by a week. "My psoriasis patients have done well with that," Dr. Armstrong said.

COVID toes and other COVID skin lesions

"Pernio-like/chilblains-like 'COVID toes' may be related to the COVID infection or not. Both can be true at the same time," said Lindy Peta Fox, MD, FAAD, professor of clinical dermatology and director of the hospital consultation services at the University of California, San Francisco. Generally, though, skin lesions associated with COVID-19 are benign and self-limited. Depending on the skin lesion, however, they can have prognostic significance. "In the inpatient setting, COVID-associated skin signs portend a worse prognosis and provide insight into the immune system's response to SARS-CoV-2 infection," Dr. Fox said.



Detecting rashes in skin of color

Cutaneous manifestations of COVID-19 are present in 0.2% to 20.5% of people with COVID, said Jenna Lester, MD, FAAD, director of Skin of Color Program at the USCF Department of Dermatology. "We saw the majority of these rashes occurring in light skin." Because skin rashes could be the only sign of COVID, it's important to recognize erythema in all skin tones. To identify erythema in skin of color, "look for dark brown and purple discoloration," Dr. Lester said. "Training your eye to see that purpura brown color is important and looking at the edges of eruption to see if you can pick up on what would be a primary color can be helpful."

COVID-19 and kids

As of early March 2022, there have been over 12 million cases of COVID in children. Although vaccines have been approved in children ages five and older, with a booster recommendation for children 12 and older, only 33% of 5-11 year-olds have received one dose, said Elena B. Hawryluk, MD, PhD, FAAD, faculty director of pediatric dermatology at the Harvard combined dermatology residency program. "One selling point for the vaccine is that multisystem inflammatory syndrome, a serious COVID complication, is more common in unvaccinated children," Dr. Hawryluk said.

The digital divide

Pre-pandemic, only 14.1% of dermatologists used telemedicine. Since COVID, it's up to 96.9%. Still, only 58% of dermatologists surveyed by the AAD said they intend to use teledermatology after COVID-19, said Jules Lipoff, MD, FAAD, assistant professor in the department of dermatology at the University of Pennsylvania. Common barriers to implementing telemedicine include technology/connectivity issues, low reimbursement, concerns regarding malpractice liability, and government regulations, Dr. Lipoff said. ●

7:18 PM !

- X BUILDING OUT TEMPLATES
- X LATE FOR DINNER YET AGAIN
- X RESPONDING TO CLINICAL STAFF
- X MISSING KID'S WINNING GOAL

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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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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.

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.

Stitch by stitch

W001 - Hands-on: Innovative Suture Techniques Update provided attendees with direct, live, and innovative instruction. Speakers shared insight into novel closure techniques with a lecture/video presentation and hands-on instruction with practice sessions.


Mark Lebwohl, MD, FAAD

AAD selects 2022 Gold Medal Recipient

Mark Lebwohl, MD, FAAD, of New York, is being awarded the 2022 Gold Medal Award at this morning's AAD/A Annual Business Meeting. Dr. Lebwohl is an internationally respected physician, scientist, and administrative leader, as well as a pioneer in immunodermatology.

In his 40-year tenure as a full-time clinician, full professor and then chair of the department at Mount Sinai, Dr. Lebwohl created one of the largest departments in the country with more than 300 voluntary and full-time physicians and scientists. Dr. Lebwohl began Mount Sinai's first phototherapy center and added three divisions: dermatopathology, surgical dermatology, and cosmetic dermatology. The department has been the national leader in research/development of nearly all biologic therapies for psoriasis, a tribute to Dr. Lebwohl's expertise and 'know-how.' His tenure as department chair ended in December when he became dean for clinical therapeutics at Mount Sinai, where the focus will be clinical research throughout the Mount Sinai system, an area he knows extremely well.

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

"I believe my greatest contribution to the specialty has been the development of psoriasis therapies and include teaching my fellow dermatologists about those therapies and fighting for patient access to those therapies," Dr. Lebwohl said.

What's causing those pediatric allergies?

Lacey Kruse, MD, FAAD

Anna Fishbein, MD

A pediatric allergist and pediatric dermatologist teamed up for Saturday's U031 – Preventing Food Allergy in Pediatric Atopic Dermatitis: Applying the New Guidelines to Your Practice. The duo provided background and case studies on food allergy in atopic dermatitis, providing references to relevant guidelines. Although they primarily focused their remarks on peanut, they also referred to milk/egg, soy, wheat, tree nut, shellfish, fish, and sesame.

"As a pediatric dermatologist, the most gratifying thing I do is to help a child overcome atopic dermatitis, which improves their quality of life," said Lacey Kruse, MD, FAAD, attending physician at Ann & Robert H. Lurie Children's Hospital of Chicago and assistant professor of pediatrics and dermatology at Northwestern University Feinberg School of Medicine in Chicago. However, applying current guidelines can be challenging, especially with the many variables of food and environmental exposures that can serve as the trigger.

Current food allergy guidelines recommend that infants with atopic dermatitis be introduced to peanut-containing foods between four to six months of age to prevent peanut allergy.

"Children should be eating food that they can tolerate," Dr. Kruse said. "Food avoidance could encourage a true allergy."

To introduce peanut to an infant, Dr. Kruse recommended adding peanut butter/powder to breast milk or formula, starting with a small amount, and monitoring the infant for 30 minutes. If there is no reaction, she suggested feeding at least two teaspoons. If tolerating, continue to feed two teaspoons of peanut butter daily.

Infants with severe eczema, egg allergy, or both should have a direct referral to allergy test or serum IgE screen; if negative, feed. If positive, refer to allergy test, and if IgE is negative, introduce peanut at four to six months.

Anna Fishbein, MD, attending physician and associate professor of pediatrics at Northwestern University Feinberg School of Medicine, defined a food allergy as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. "The key is reproducibly," she said. Lactose intolerance, food protein-induced proctocolitis, behavioral changes with foods, fever, or mild diarrhea are not food allergies.

Not all allergens are the same, she said. For example, baked milk or egg can help an infant outgrow an egg allergy, roasting peanuts makes them more allergenic, and fish and shellfish are most easily aerosolized, which makes reactions around cooking common.

Dr. Fishbein provided her pearls on food-triggered eczema. "Consider practical thinking," she said. "If there is no peanut in the diet or the home, it is not triggering eczema.

"It can be confusing because even IgE-mediated reactions cause eczema flare. We see this after food challenges all the time," she said. She also noted that food patch testing is not predictive.

As takeaway items, Dr. Kruse recommended introducing peanut into patients with mild-to-moderate atopic dermatitis at four to six months of age, have an allergist on tap to help with challenging patients — especially those with severe atopic dermatitis — and decide if you are comfortable introducing testing versus referring infants with severe atopic dermatitis.

WHAT'S HOT?

Is it hot in here, or just the topics?

Can emollients prevent the first onset of atopic dermatitis in high-risk newborns? That was the first of many exciting questions answered in Saturday's S038 – Hot Topics, led by David Eric Cohen, MD, FAAD.

Eric Simpson, MD, MCR, FAAD, professor of dermatology at Oregon Health & Science University, kicked off the session by presenting information on atopic dermatitis pathogenesis and evidence suggesting that it can't be prevented from the outside in.

"So far, it hasn't panned out. But I'm not giving up," Dr. Simpson said. Still, evidence shows you can reduce the severity of the atopic disease progression in infants with proactive therapy started within four months of diagnosis.

Who should use JAK inhibitors?

"JAK inhibitors are potent therapies for biologic failures," Dr. Simpson said. They are not recommended for patients with a history of clotting risks, cancer, serious infection, severe renal or liver disease, or significant cardiovascular disease. Avoid prescribing a JAK inhibitor to patients who are pregnant or breastfeeding, but pick patients carefully, engage in shared decision-making, and do not use during pregnancy or lactation. Patients should review the medication guide. JAK inhibitors provide amazing results if used properly in the right patient," he said.

New help for hair loss

Does low-dose oral minoxidil work better than topical minoxidil? Since 2015, low-dose oral minoxidil — 10 mg or less daily — has become almost routine for dermatologists to use for various hair conditions, said Jerry Shapiro, MD, FAAD, professor at NYU Grossman School of Medicine. Dr. Grossman presented evidence that low-dose oral minoxidil can benefit patients with androgenetic alopecia and alopecia areata. Dr. Shapiro also presented new evidence on the efficacy of baricitinib. "This will become the first FDA-approved medication for alopecia areata," Dr. Shapiro said. Doses of 4 mg and 2 mg show significant results in clinical trials, compared to placebo, with low side effects.

Ritlecitinib is another JAK inhibitor on the horizon. There is no cure for alopecia areata. "But these JAK inhibitors will be game changers. Eyelashes and eyebrows regrew in many people," Dr. Shapiro said. "I tell patients: 'Your hair is not dead. It's sleeping. We need something to wake it up.' These JAK inhibitors seem to wake it up in many patients."

Lasers and energy-based therapies

Highlighting new technologies on the horizon, "there's a lot in the pipeline," said Murad Alam, MD, FAAD, vice chair in the department of dermatology at Northwestern University in Chicago. "Many use AI and other similar technologies to improve the targeting of lasers. It's a matter of zapping exactly what you want," Dr. Alam said. New laser devices on the horizon include combination C02157 nm ablation and tightening and imaging-directed selective dermal laser treatment. "The device uses next-generation 3D precision laser and high-resolution imaging," Dr. Alam said.

Be on the lookout for non-laser devices as well, such as nitrogen-derived plasma technology — plasma that can cause epidermal and dermal remodeling. Robotics will also be a big part of the future, such as the robotic no-contact 1064 nm diode for lipolysis. It's laser technology that doesn't touch the skin or cause pain like contact 1064 nm lasers can. But don't worry that robots will replace dermatologists. "We will still be the leaders to use the technologies to help our patients get better outcomes," Dr. Alam said.

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Model represents moderate-to-severe disease.

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(tralokinumab-ldrm)
Injection 150 mg/mL

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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.

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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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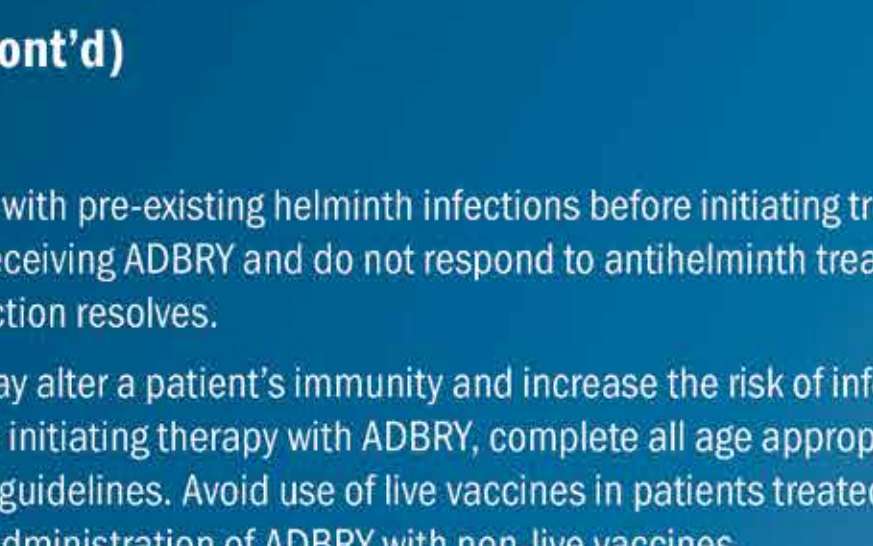

Adbry™
(tralokinumab-ldrm)
Injection 150 mg/mL

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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Enhancing the naked eye with medical imaging

Photographic images have long been a useful record of dermatologic changes. Advancing technology — combined with growing awareness of the value of clinical imaging — is transforming a useful record into a must-have, must-use clinical tool.

Paola Pasquali, MD, IFAAD, coordinator of dermatology at Pius Hospital in Valls, Spain

Dr. Pasquali will moderate **F067 – How Far Can We Get With Medical Imaging** to explore how far imaging technology has already taken dermatology and how the practice is likely to evolve. For far too long, dermatologists have relied on eyesight and paid too little attention to imaging modalities developed by other specialties.

> "Just as a radiologist can diagnose breast cancer from a mammographic image seen through a monitor, dermatologists — who are by far the most visual of medical specialists — need to learn to do likewise."

UPCOMING SESSION
F067 – How Far Can We Get With Medical Imaging
Saturday, March 26 | 3:30 – 5:30 p.m.
Room 109B

Beyond the clinical eye

"A radiologist or an endoscopist would be thrilled if you offered a new gadget to their armamentarium that would allow them to improve their diagnostic capacities," Dr. Pasquali noted. "Dermatologists have relied on their eyes. Just imagine the change in the treatment of keratinocyte tumors if we know beforehand the depth and shape."

Dermatologists have been using photographs to document, diagnose, monitor, and follow up on treatment outcomes since glass plates were the newest technology in the 19th century. Photographs have been familiar teaching tools for nearly two centuries, a role that continues to grow as new imaging modalities come into clinical practice.

Advances in dermoscopy

Dermoscopy is the second most common imaging modality in dermatology, Dr. Pasquali continued. From the early use of surface microscopy in the 1920s, dermoscopy now allows dermatologists to magnify and visualize subepidermal structures. High-frequency ultrasound, reflectance confocal microscopy, and optical coherence tomography (OCT) are bringing deeper and more detailed views into practice.

"The naked eye is simply not sufficient," Dr. Pasquali said. "We need to go beyond the visible and obtain as much information as possible to make more precise diagnoses and make the most appropriate decisions for each condition."

Adopting new technologies

All of these novel imaging approaches meet real medical needs, she said. Some clinicians use confocal microscopy as a noninvasive biopsy, an in vivo assessment of cellular morphology. Ultrasound and OCT provide detailed information about the volume, shape, and depth of invasion of tumor diseases. Those same approaches can be used to more accurately diagnose and monitor inflammatory reactions to aesthetic fillers.

Cost is always a consideration in adopting new technologies, Dr. Pasquali added. New imaging modalities are no exception. One approach is to incorporate multiple imaging techniques into one piece of equipment: photography and ultrasound, confocal plus photography plus dermoscopy.

"The synergistic effects of combining two or more techniques enhances their diagnostic impact and practicability," she said. "Excellent cameras are already part of mobile phones, and attachments for mobiles make it possible to use and take images from any brand of dermoscope. There is already a prototype for a mobile confocal microscope — it is just a matter of time."

Fox Award: The future of dermatology recognized

Congratulations to all who participated in the 2022 Resident and Fellows Symposium!

The Resident and Fellows Symposium was held Saturday, during the 2022 Annual Meeting in Boston, led by Cory A. Dunnick, MD, FAAD. Faculty judges selected individuals who presented the most outstanding papers in laboratory and clinical research. The winners of this year's prestigious Everett C. Fox Memorial Award are:

Basic Science Category

Winner: Mairead Baker, MD
Institution: Department of Dermatology, Medstar Washington Hospital Center/Georgetown University Hospital, Washington, D.C.
Title: CD200 expression on Merkel cell carcinoma enhances anti-inflammatory M2 macrophage polarization

Winner: Touraj Khosravi-Hafshejani, MD
Institution: University of British Columbia, Department of Dermatology and Skin Science, Vancouver, BC, Canada
Title: Inhibition of tissue resident memory-T cells as a therapy for contact hypersensitivity

Clinical Category

Winner: Maggi Ahmed Refat, MD
Institution: University of Massachusetts Medical School, Worcester, Massachusetts
Title: A double-blinded randomized placebo controlled study to examine the efficacy of JAK or calcineurin inhibitors added to phototherapy to promote melanocyte transplantation in the treatment of vitiligo

Winner: Andressa Akabane, MD, MMSC
Institution: University of Massachusetts Medical School, Worcester, Massachusetts
Title: Characteristic skin features in small-fiber polyneuropathy

Winner: Alan Snyder MD, MSCR
Institution: Medical University of South Carolina Department of Dermatology and Dermatologic Surgery, Charleston, South Carolina
Title: Histologic screening of malignant melanoma, spitz, dermal, and junctional nevi using a using a deep learning model

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Nutrition's part in good skin health

Are your patients malnourished? Very possibly, even if they are overweight or obese. Americans tend to be terrible eaters, or don't eat enough of the right things.

"Overweight and obese individuals may be malnourished in other ways," said Martina Cartwright, PhD, MS, director of continuing professional education at the University of Arizona School of Nutritional Sciences and Wellness in Tucson, Arizona.

Dr. Cartwright focused on the latest evidence in the role of essential nutrients in skin health as part of the session **F061 – The Role of Nutrition in Skin Health**, led by Wilma Bergfeld, MD, FAAD. Most Americans get enough B vitamins, Dr. Cartwright explained, but tend to lack vitamins C and D, as well as sufficient iron and other micronutrients essential to skin and hair health.

"Skin issues may appear with over- or under-nutrition," Dr. Cartwright said. "Too much or too little of a particular nutrient can result in skin problems, including hair issues."

Martina Cartwright, PhD, MS, director of continuing professional education at the University of Arizona School of Nutritional Sciences and Wellness in Tucson, Arizona

The meal pattern that seems to benefit the skin the most is the Mediterranean diet. It is anti-inflammatory and micronutrient rich, with a good balance of micronutrients.

"Fostering better nutritional habits takes time and patience. Change starts with small changes and encouragement."

– Dr. Cartwright

IN ADDITION

The two-hour session on nutrition also featured Dr. Bergfeld discussing nutrition for health hair and scalp; nutrition's role in the development of acne, rosacea, and other skin conditions presented by Seemal R. Desai, MD, FAAD; and a presentation on the impact of nutrients and dietary patterns on aging by Emmy M. Graber, MD, MBA, FAAD.

Overweight and obesity cause chronic, smoldering inflammation, which may impact the severity and incidence of some skin problems.

Inflammation is central to many, perhaps most, skin disorders, and the influence of dietary patterns varies with the skin disease involved.

Skim milk and other dairy products (not including yogurt or cheese) and high glycemic foods may **aggravate acne**, for example.

Psoriasis is linked to obesity, elevated serum glucose levels, and cardiovascular disease risk.

Rosacea is exacerbated by spicy and hot foods and may be aggravated by cola, soy, processed meats, and other foods rich in histamine.

On a positive note, HMB, beta hydroxy beta methyl butyrate, a metabolite of leucine, can profoundly improve **wound healing**.

Overconsumption of calories often goes along with underconsumption of key nutrients — balance is critical.

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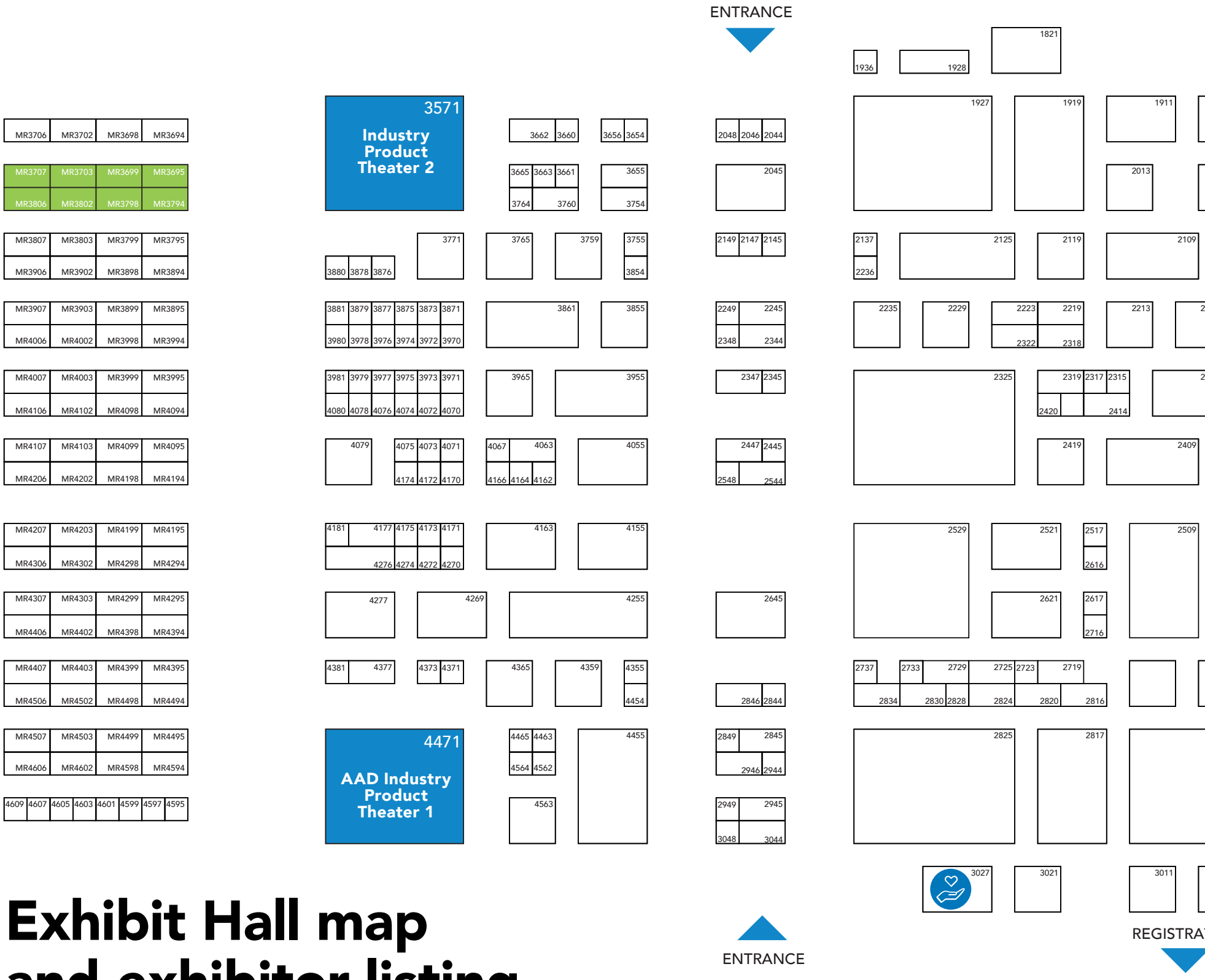
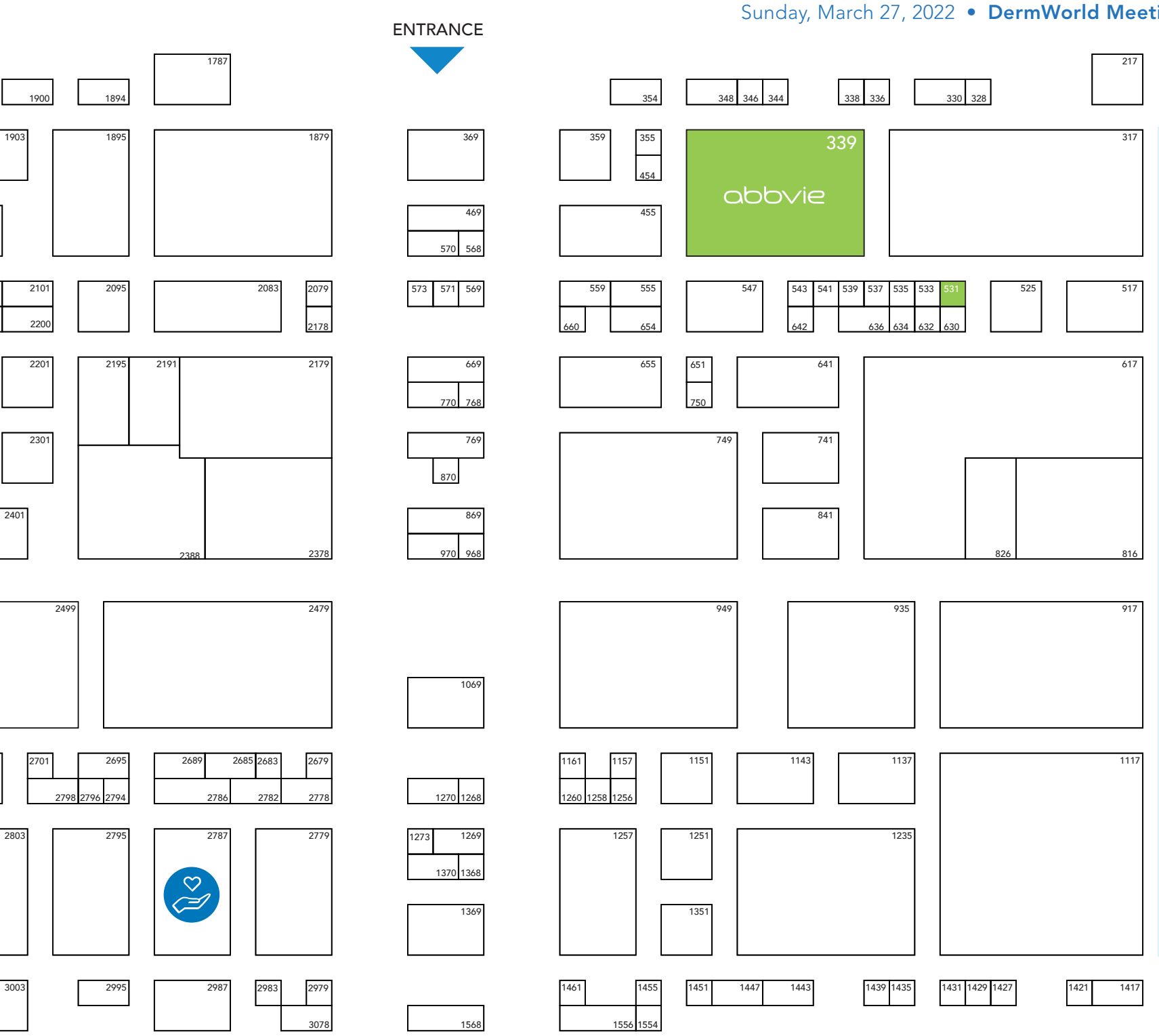


Exhibit Hall map and exhibitor listing

Data current as of Feb. 25, 2022. Please use the AAD Meeting App **aad.org/mobile** for the most up-to-date exhibitor list.



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

AAD Poster Exhibits Viewing
003

= AAD Cause Supporter booth
See box at bottom of page 15 for more details.

GluStitch Inc. 2204
Golden State Dermatology 3977
Greenway Therapeutix 2249
Health Professionals Alliance 3879
HEINE 2315
Henkel USA 2307
Hidrex USA 537
HydraFacial 2301
Ibero Latin American Collage of Dermatology/CILAD 2548
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Infinity Massage Chairs 1268
Inform Diagnostics 2828
Inga Ellzey Billing Companies 3654
Innovaderm Research 2213, MR3998
Innovation Compounding 4272
Integrated Dermatology Group 2083
International Society of Dermatology 2079
IntraOp Medical Corporation 3765
JAMA Network, The 2737
Jan Marini Skin Research, Inc. 3078
Janssen Biotech, Inc. 749, 1369, MR4395, MR4399, MR4403, MR4407
Johnson & Johnson Consumer Inc 816
Journal of Clinical and Aesthetic Dermatology 535
Kaiser Permanente 2044
Keystone, Inc. 1258, 2317
KitoTech Medical 4373
Klara Technolgies 2145
Klotho Skin LLC 4355
Krystal Biotech 2946, MR4498
La Roche-Posay 2388
LASEROPTEK Co., Ltd. 369
Laservision 2319
LearnSkin 1260
LEO Pharma Inc. 1927, MR3995, MR3999, MR4003, MR4007
Lilly USA, LLC 2325, MR3902, MR3906
LocumTenens.com 336
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NAOS/Laboratoire Bioderma 1928
National Eczema Association 4071
National Psoriasis Foundation 338
NeoStrata Company, Inc. 826
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see EXHIBITOR LISTING page 15

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continued from page 13

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DEI efforts intensify within dermatology

Although the field of dermatology has made steady progress in addressing diversity, equity, and inclusion (DEI), there's more work ahead. But there are also increasing numbers of physicians who are committed to the effort.

Kanade Shinkai, MD, PhD, FAAD, a dermatologist with the University of California San Francisco Health

Henry W. Lim, MD, FAAD, AAD past-president and dermatologist at Henry Ford Hospital in Detroit

The goal of more comprehensive DEI is within reach, according to Kanade Shinkai, MD, PhD, FAAD, a dermatologist with the University of California San Francisco Health, and Henry W. Lim, MD, FAAD, AAD past-president and dermatologist at Henry Ford Hospital in Detroit. Drs. Shinkai and Lim are co-chairs of the session, **S023 – Diversity, Equity, and Inclusion**, which highlights the importance of DEI in dermatology and the efforts underway to improve it.

"Dermatology is the second least-diverse specialty in the house of medicine with regard to race and ethnicity," Dr. Shinkai said. "However, there are tremendous efforts happening in dermatology to broaden diversity, inclusion, and equity in this specialty, including gender/sexual orientation, race, ethnicity, religion, and ability status."

"Structural racism and unconscious bias, for example, can affect our diagnostic evaluation and management of patients with skin disease," Dr. Lim said.

To address these issues, dermatology is already making strides to acknowledge and improve its commitment to DEI through key initiatives, Dr. Lim said. These include:

- Partnerships among dermatology leadership groups to improve DEI, including AAD, the Association of Professors of Dermatology (APD), the Skin of Color Society (SOCS), the Society for Investigative Dermatology (SID), the Women's Dermatological Society (WDS), and the AAD LGBTQ/Sexual and Gender Minorities (SGM) Expert Resource Group.
- Diversity-focused conferences and meeting sessions, including the DEI session at the Annual Meeting and the AAD Diversity Champions Workshop.
- Increased awareness and recommendations to increase representation of images of skin conditions in diverse populations in textbooks, journals, curricula, and in presentations for speakers at AAD meetings.
- Programs to develop content related to DEI and social determinants of health, including the new AAD Skin of Color curriculum.
- DEI taskforces and committees within dermatology organizations, state societies, and academic dermatology departments.
- A holistic review framework that is more widely used by dermatology residency programs to select residents.
- Increased content in key dermatology journals that focuses on DEI and health care disparities.

Drs. Shinkai and Lim agree that these initiatives, combined with a wide spectrum of mentorships, sponsorships, allyship building, research, education, advocacy, and leadership in dermatology will help dermatologists move the needle toward improved DEI and patient care.

A lack of DEI in the specialty has a potential direct impact on the daily work of dermatologists as well as every key mission of the work they do, including:

Navigate the 2022 Annual Meeting from your mobile device! aad.org/mobile
session schedules | exhibitor information | CME | session evaluations | and much more

AAD Career Networking Event

Annual Meeting attendees took advantage of in-person networking with hiring companies and industry professionals at the Career Networking Event. The event was held on Friday at the Westin Boston Seaport.

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TODAY'S TOP TWEETS
#AAD2022 @AADmember

Late-breaking research: Paola Facheris, MD, discussed "Oral Difelikefalin Improves Itch and Inflammatory Biomarkers in Atopic Dermatitis Subjects With Moderate-to-Severe Pruritus"

Mount Sinai Dermatology
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Very appreciative to be awarded both the AAD Young Investigator Award for Bench/ Translational Research and the @SkinofColor Society Career Development Award today. Excited to keep building our research program

Shawn Kwatra, MD, FAAD
@drshawnkwatra

So honored to present my work about small-fiber polyneuropathy in the #AAD2022 Annual Meeting in Boston! Look forward to learning best #dermatology practices, strategies, and skills in this amazing event!

Andressa Akabane, MD, MMSC
@andressaakabane

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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).

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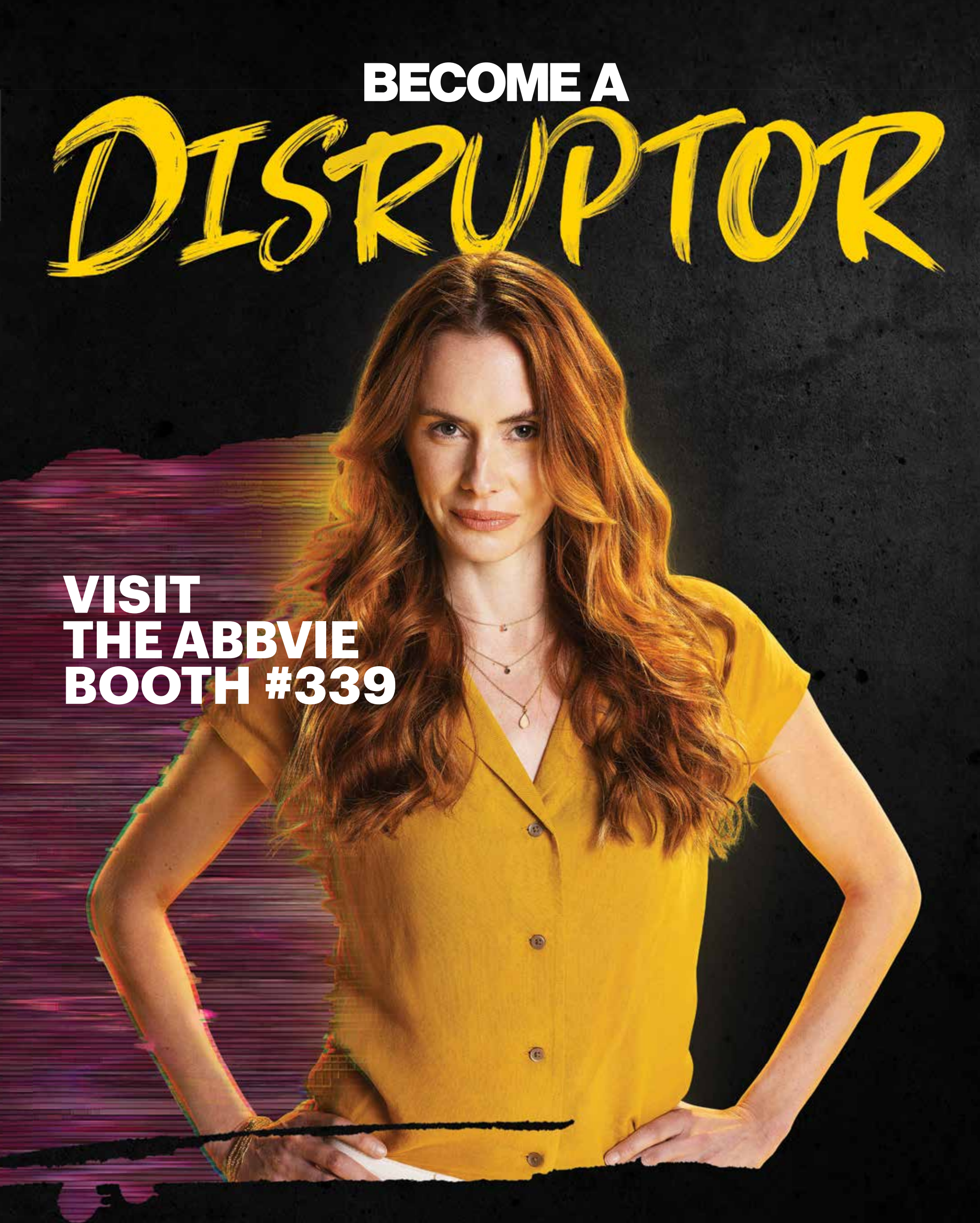

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