AAD

DermWorld meeting news

FRIDAY. MARCH 25, 2022

A Publication of the American Academy of Dermatology | Association

INSIDE

LATE-BREAKING IN BOSTON

Late-Breaking Research sessions showcase clinical trial results in recent, unpublished abstracts.

Attendees will get a first-hand account of the latest ground-breaking scientific developments in dermatologic research and be able to evaluate and apply information from recent investigations to their own clinical practices.

This year's Late-Breaking Research lineup includes:

F045 – Late-Breaking Research: Clinical Studies/ Pediatric
Saturday, March 26
9–11 a.m.
Location: 253A

S026 – Late-Breaking Research: Clinical Trials
Saturday, March 26
9 a.m. – 12 p.m.
Location: 210A

F055 – Late-Breaking Research: Procedural Dermatology
Saturday, March 26
1–3 p.m.
Location: 107A

F068 – Late-Breaking Research: Basic Science/ Cutaneous Oncology/ Pathology
Saturday, March 26
3:30–5:30 p.m.
Location: 205A

It's good to be back!

Welcome to Boston and the return of the Annual Meeting in its traditional live format! This is the first time an AAD Annual Meeting has been held in Boston, and it features more than 300 educational sessions ranging from large symposia and courses to intimate focus sessions and hands-on workshops.

The AAD has more than 1,000 expert speakers lined up over the next few days to cover every facet of dermatology, and the comprehensive program will feature its usual host of favorite sessions, like **Hot Topics**, **What's New in Dermatology**, live/hands-on demonstrations, and four new **Late-Breaking Research** symposiums, among others.

We've added multiple new, highly anticipated sessions as well, including T**he 2022 Debates: Controversies in Dermatology; COVID-19 Dermatology and Vaccines; a new hands-on session for patch testing**, *JAAD* **Game Changers**; and an **exam prep course for MDS certification**, offered for the first time at an AAD Annual Meeting.

The Plenary also returns on Sunday, with the Clarence S. Livingood, MD, Memorial Award and Lectureship; the Eugene J. Van Scott Award for Innovative Therapy of the Skin and Phillip Frost Leadership Lecture; the Lila and Murray Gruber Memorial Cancer Research Award and Lectureship; the Marion B. Sulzberger, MD, Memorial Award and Lectureship; and, new for 2022, the John Kenney, MD, Memorial Award and Lectureship. Special invited speakers are back for more **Derm Tales** during the Plenary and noted author and lecturer Doris Kearns Goodwin is our guest speaker.

"Stimulating lectures abound," said David M. Ozog, MD, FAAD, FACMS, chair of the AAD Scientific Assembly Committee. "There are ample opportunities for Q&A and courses, symposia, forums, and focus sessions on myriad topics, including dermatopathology, medical, pediatric, and surgical dermatology."

Getting your CME

Remember, all education sessions offer an engaging and up-to-date look at dermatology, with ready-to-apply tips and takeaways. Attendees can earn MOC self-assessment credits when they attend sessions utilizing an Audience Response System or a hands-on session.

Complete list of sessions

Session information including the complete schedule and speakers will be available at **am2022.aad.org/** sessions and regularly updated.

Vibrant Exhibit Hall awaits you

While you're here, make time to explore the latest products and services from over 300 exhibitors, including those specializing in equipment/ devices, pharmaceuticals, publishing, recruiting, and more. The Exhibit Hall features unopposed hours during the meeting on Friday, Saturday, and Sunday from 12-1 p.m.

You'll also want to stop by the AAD Resource Center, booth #2529, to learn more about AAD member benefits and shop the Academy's practice management resources, patient handouts, and professional education activities.

More of your favorites

There are other exciting events planned, like the AAD Career Fair this evening, and an exciting array of Industry Non-CME (INC) Programs today through Sunday, March 27. ●

Follow us!

Follow **@AADmember** on Facebook, Instagram, and Twitter. Use the hashtag **#AAD2022** to engage with your colleagues and share your meeting experience.

12:32PM !

- X WORRYING ABOUT OPERATIONAL METRICS
- X FORGETTING TO DEDUCT RETINOL SALE
- X MULTIPLE PATIENTS ON HOLD
- X COLD, SOGGY SANDWICH

It's about time you took a lunch break

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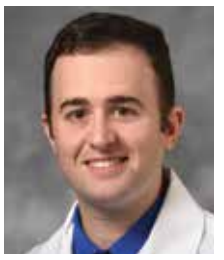
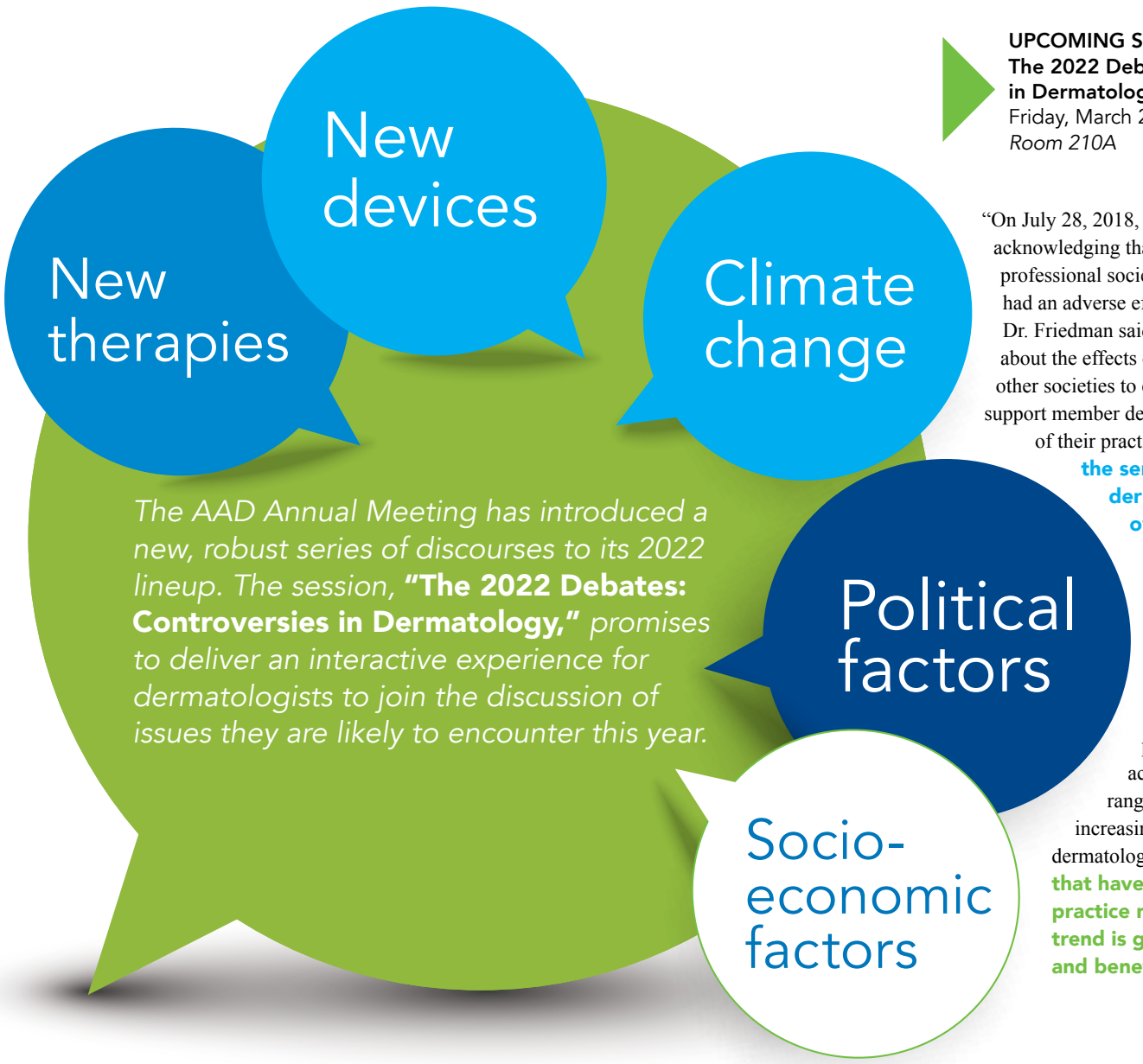
The great debates begin today!

New devices, therapies, and socio-economic and political factors as well as new ways of thinking about the dermatology profession encourage discourse.



Ben Jacob Friedman, MD, FAAD, a dermatologist with the Henry Ford Health System in Detroit, moderates the debate, which will run the gamut from clinical to professional and everything in between, including climate change.

UPCOMING SESSION
The 2022 Debates: Controversies in Dermatology (S017)
Friday, March 25 | 1-4 p.m.
Room 210A



The AAD Annual Meeting has introduced a new, robust series of discourses to its 2022 lineup. The session, ***"The 2022 Debates: Controversies in Dermatology,"*** *promises to deliver an interactive experience for dermatologists to join the discussion of issues they are likely to encounter this year.*

"On July 28, 2018, the Academy issued a position statement acknowledging that there is strong consensus among various professional societies of physicians that climate change has already had an adverse effect on the health and wellbeing of Americans," Dr. Friedman said. "The AAD also resolved to raise awareness about the effects of climate change on skin health, work with other societies to educate the public and mitigate the problem, and support member dermatologists in decreasing the carbon footprint of their practices in a cost-effective way. **"We will debate the seriousness of the problem, and whether dermatologists should prioritize this effort over other problems facing the specialty in current times,"** he said.

External business and political activism factors around the profession of dermatology are likely to stir further debate, Dr. Friedman said. He pointed out that conversations over private equity acquisition of dermatology practices will fuel a range of opinions. "Private equity firms have been increasingly acquiring physician practices, and in particular, dermatology," he said. **"We will examine the forces that have contributed to this increasingly common practice model and critically analyze whether this trend is good for dermatology, healthy for patients, and beneficial for the American public."**

Up for Debate

Appropriate indications and use of oral antibiotics for acne, dupilumab for severe dermatitis, and PRP for hair loss.

Antibiotics in acne

The optimal way to use antibiotics for the treatment of acne vulgaris has long been debated. The most recent AAD guidelines from 2016 discourage the use of antibiotics as monotherapy. They also emphasize the importance of using topical benzoyl peroxide in conjunction with topical and oral antibiotics to limit development of resistance to cutibacterium acnes. "We will debate whether these considerations are sufficient or substandard for achieving antibiotic stewardship," Dr. Friedman said.

Dupilumab for atopic dermatitis

The most recent AAD treatment guidelines for atopic dermatitis were published in 2014. Since that time, dupilumab, a monoclonal antibody blocking the shared receptor for IL-4 and IL-13, was approved by the FDA for the treatment of moderate-to-severe atopic dermatitis (in 2017 for patients aged 12 and older, and in 2020 for children aged 6-11). This drug represented a major breakthrough in the treatment for atopic dermatitis and is the first biologic to have ever been approved for this common, debilitating condition.

"Optimal prioritization of dupilumab in the treatment algorithm for children and adults with atopic dermatitis is now up for debate. Furthermore, with increased utilization over the past few years and the more recent approval of topical and oral JAK inhibitors and tralokinumab (pure IL-13 antagonist), it remains to be seen whether this drug will become and/or remain the first-line therapy for moderate-to-severe atopic dermatitis," Dr. Friedman said.

PRP for hair loss

Treatment of androgenetic alopecia remains difficult and only two FDA-approved therapies (oral finasteride for males and topical minoxidil for both males and females) exist. Platelet-rich plasma (PRP) has been widely investigated as a potential, effective treatment for several dermatological conditions, including androgenetic alopecia. There have been several studies demonstrating efficacy for PRP in this condition in both men and women. However, standard protocols for preparation and administration as well as methods for evaluating results have not been established which (along with cost issues) limits its widespread adoption. Is PRP truly "revolutionizing" the treatment of androgenetic alopecia or not?

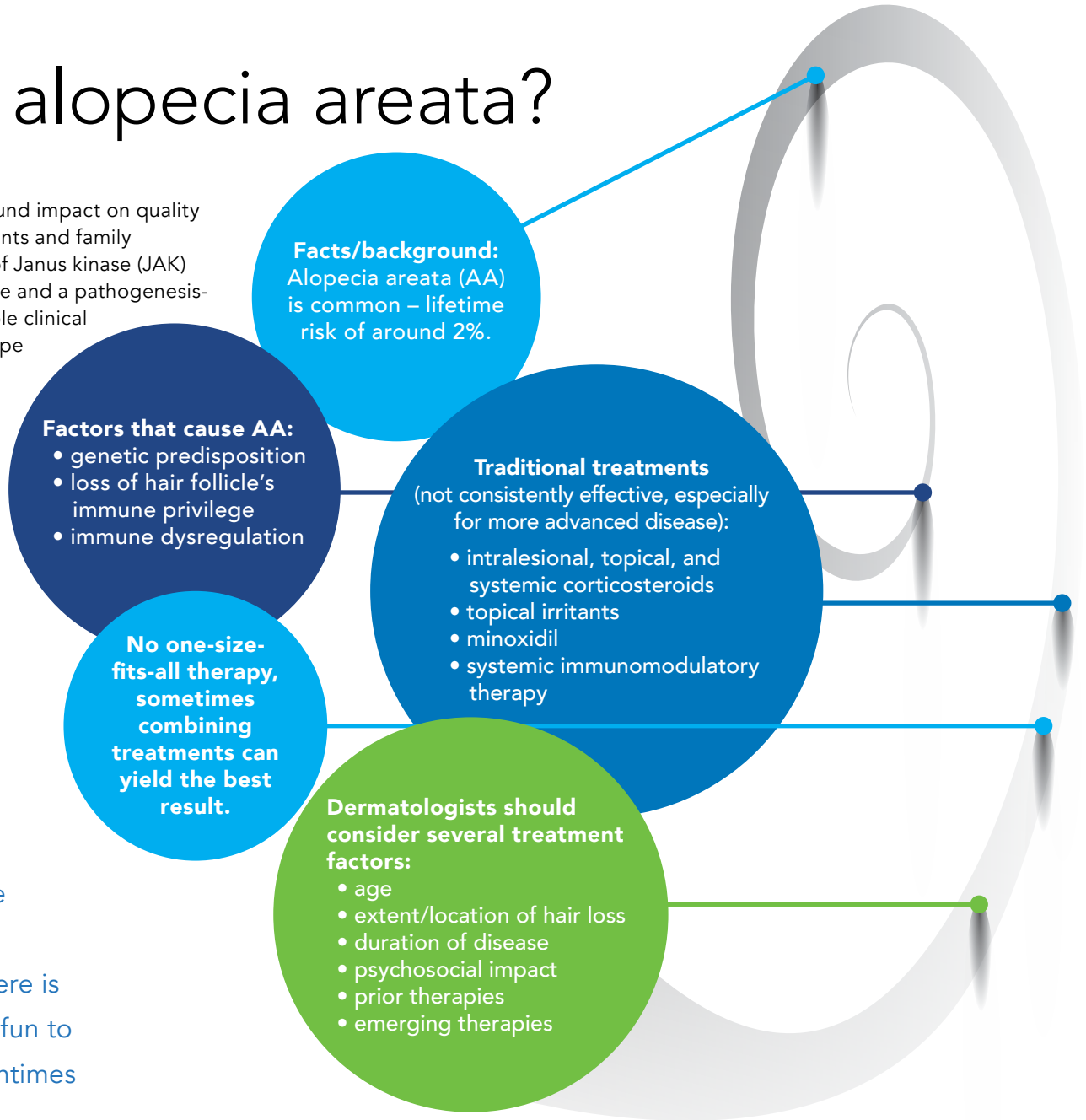
What to do about alopecia areata?

Although it remains a complex disease, more effective and reliable treatments for alopecia areata may be on the horizon.

Key point:
Alopecia areata has a profound impact on quality of life of both affected patients and family members. The emergence of Janus kinase (JAK) inhibitors represents promise and a pathogenesis-directed therapeutic. Multiple clinical trials have demonstrated hope for JAK inhibitors, but these medicines carry risk for potential serious adverse effects.

U012 – Alopecia Areata Power Hour
Friday, March 25 | 4:30 - 5:30 p.m.
Room: 253A

Brittany Craiglow, MD, FAAD, associate professor of dermatology at Yale University School of Medicine. Dr. Craiglow will offer a new perspective on this devastating disease.



"Although treating patients with AA can be challenging, it is also extremely rewarding. The changing therapeutic landscape means that there is now hope for these patients, and it is so much fun to be able to help them get their hair — and oftentimes their lives — back."

Don't miss the 2022 AAD Career Networking Event
Friday, March 25 | 4:30-6:30 p.m.
Location: Westin Seaport Hotel, Grand Ballroom A

PRODUCT SHOWCASE

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).

EXPERT ADVICE AND EDUCATION

Not an actual patient.

Model represents moderate-to-severe disease.

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

NOW AVAILABLE

Join LEO Pharma and a leading dermatology expert at the following exciting non-CME program:

PROMOTIONAL LUNCHTIME PRODUCT SESSION

A NEW TREATMENT FOR ADULTS WITH UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

MATTHEW ZIRWAS, MD
Dermatologists of Central States

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

JOIN THE ADBRY™ EXPERIENCE AT **BOOTH 1927**

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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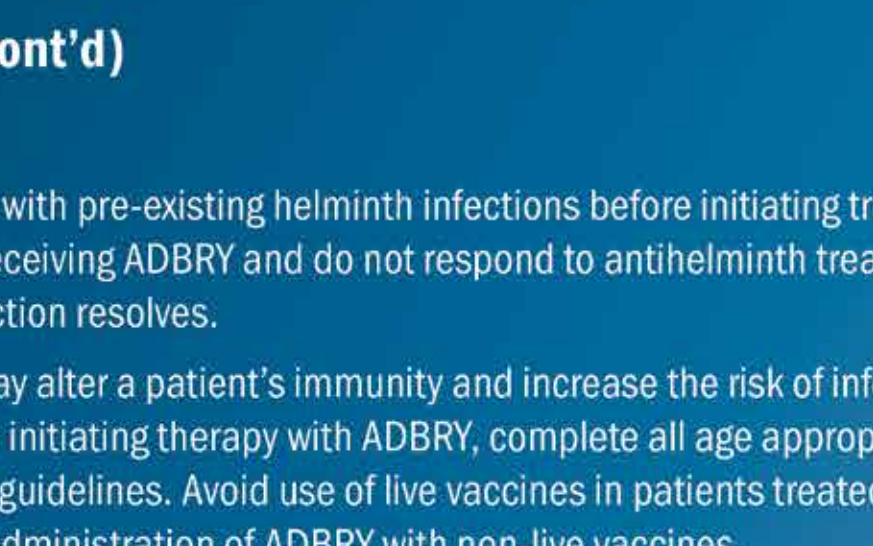

Adbry™
(tralokinumab-ldrm)
Injection 150 mg/mL

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.

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A new vision for effective practice management

Tom Helm, MD, FAAD, clinical professor of dermatology and pathology at Jacobs School of Medicine in Buffalo, New York, takes attendees through the steps of practice management.

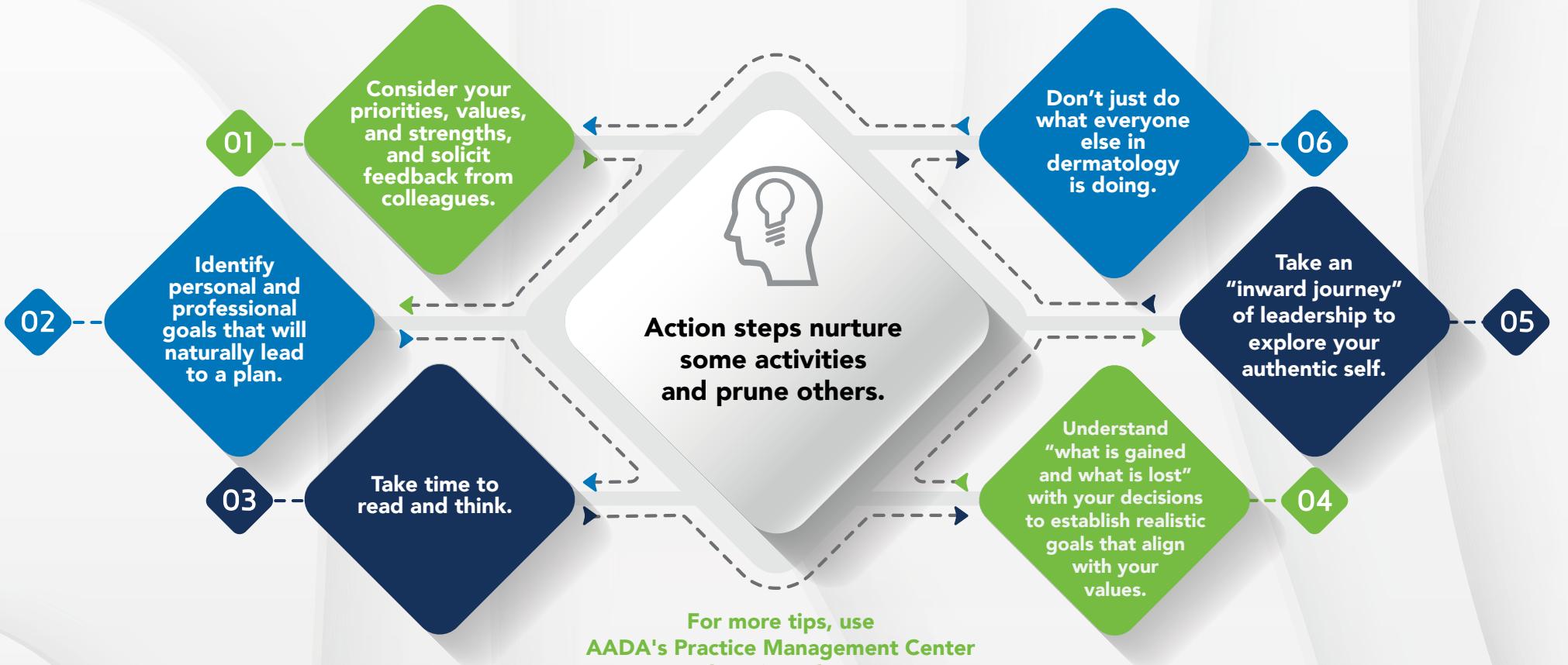
UPCOMING SESSION
S015 – Practice Management: Vision, Execution, and Optimization
Friday, March 25 | 1 – 4 p.m.
Room 103

Charting a course for the future of your practice takes vision. Although dermatologists may have the clinical expertise to excel in the specialty, sharpening your business skills is an important counterpart for advancing your practice.

Tom Helm, MD, FAAD, and a panel of experts including Jeffrey Miller, MD, FAAD, Robert Kalb, MD, FAAD, Alexandra Flamm, MD, MPH, FAAD, Mollie A. MacCormack, MD, FAAD, Melissa Piliang, MD, FAAD, and Alexa Boer Kimball, MD, MPH, FAAD, will dissect the tasks at hand, helping attendees formulate a vision for their practice, outline actions to implement their vision, and identify strategies for adjusting to a changing health care environment. Panelists, including Dr. Helm, will share their own approaches.

"Most dermatologists have a vision for their practice, but most do not allocate time to formulate specific actionable goals and steps for implementation," Dr. Helm said. "Reacting to stressors and pressing problems often takes time and resources away from long-term planning, relationship building, and focusing on personal growth."

When formulating a practice management plan, Dr. Helm encourages dermatologists to outline steps to implement their vision and identify strategies for adjusting to a changing health care environment. Dr. Helm's steps include:



For more tips, use AADA's Practice Management Center www.aad.org/member/practice

"These Academy opportunities have provided me with valuable perspectives and renewed my will to actively make changes in my practice."

– Dr. Helm

During this afternoon's comprehensive session, panelists will delve into several practice management sub-topics, including:

- Navigating networks and organizational culture while staying at your "True North."
- Translating your vision into practice.
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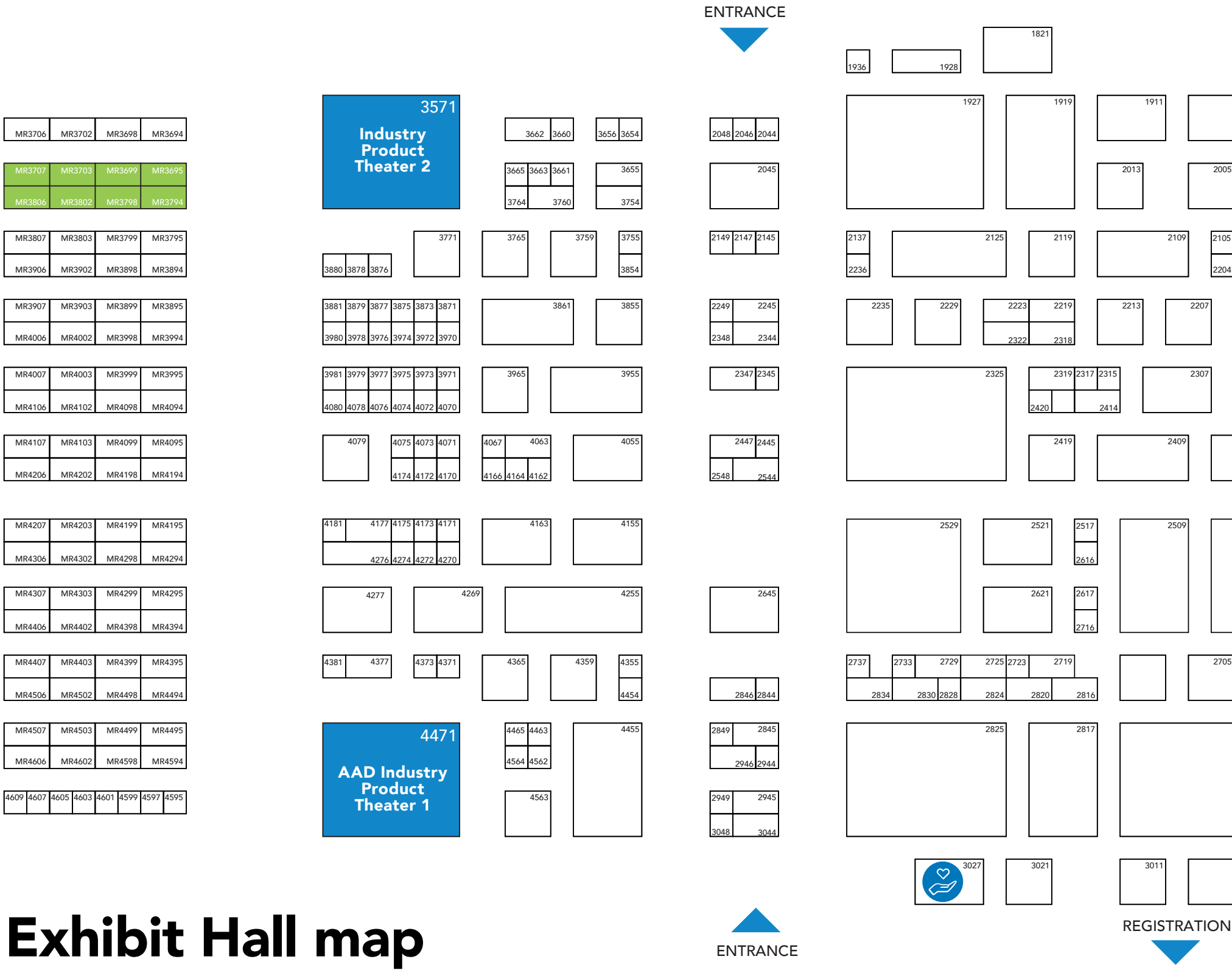
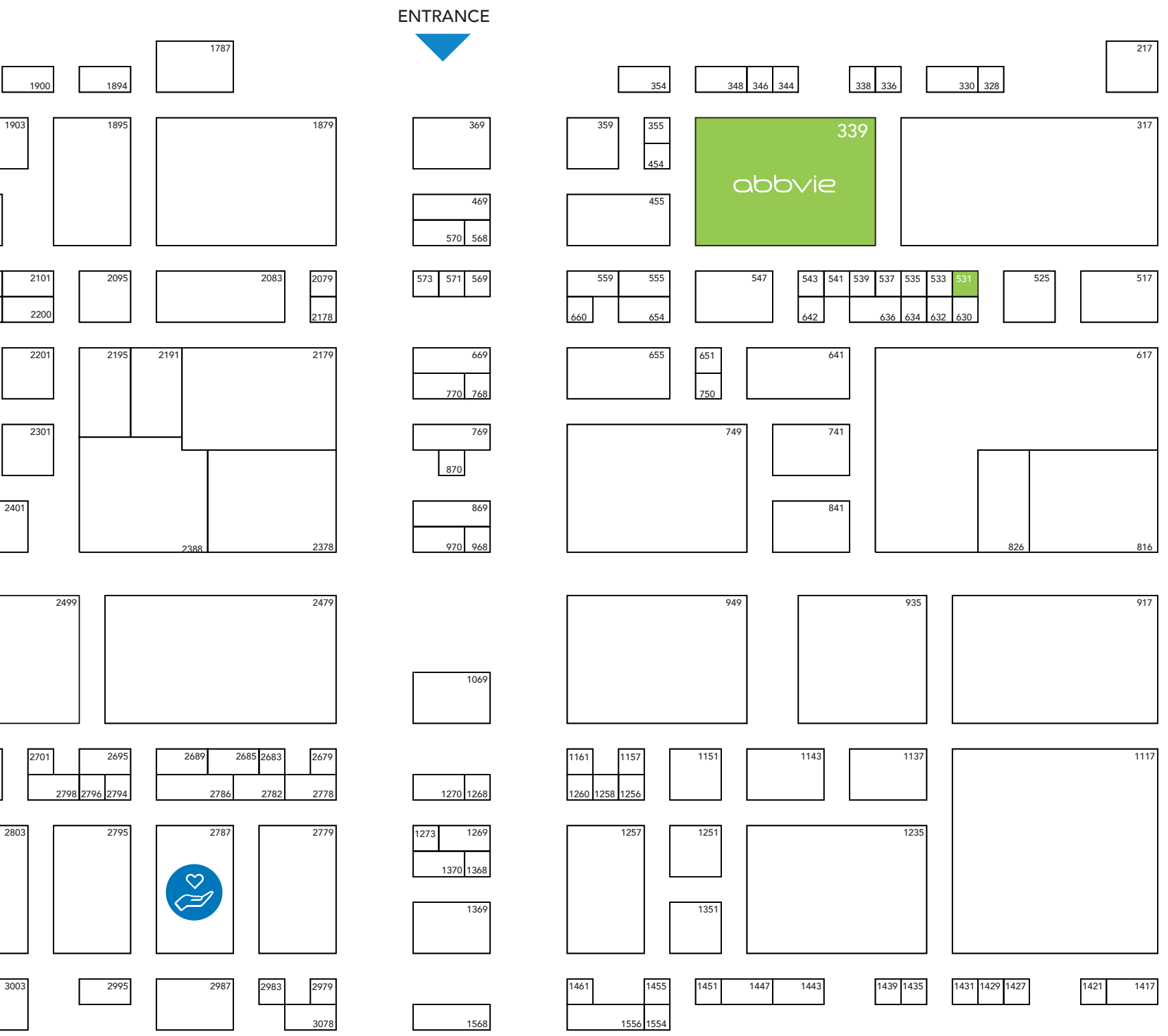


Exhibit Hall map and Exhibitor Listing

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

see EXHIBITOR LISTING page 15

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EXHIBITOR LISTING

continued from page 13

TODAY'S HIGHLIGHTS

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

9 a.m. – 12 p.m.
S001 - 2019 AAD/NPF Guidelines
Location: 209

S007 - Optimize Your Practice: Getting It Right and Loving Your Job!
Location: Room 151B

S008 - Pearls: Diagnostic and Therapeutic
Ballroom East

9 a.m. – 4 p.m.
C001 - Conquer the Boards: An Experiential Review (ticket required)
Location: 157 C

9 a.m. – 5 p.m.
S005 - Gross and Microscopic Symposium
Location: 105

10 a.m. – 5 p.m.
Exhibit Hall and AAD Resource Center open

12 p.m. 1 p.m.
Unopposed Exhibit Hall Hours

1 – 4 p.m.
S014 - Managing Tough Real Life Dermatology Cases
Location: 209

S015 - Practice Management: Vision, Execution, and Optimization
Location: 103

S016 – Psoriasis
Location: Ballroom East

S017 - The 2022 Debates: Controversies in Dermatology
Location: 210A

S019 - Acne and Rosacea
Location: Ballroom West

4:30 - 6:30 p.m.
Career Networking Event (registration required)
Westin Boston Seaport Hotel, Grand Ballroom A

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Boehringer Ingelheim - Booth 2787
Proudly supporting Public Education on Generalized Pustular Psoriasis.

There's plenty for residents at the AAD Annual Meeting in Boston

The AAD has a lot to offer residents at the 2022 Annual Meeting in Boston. Designed for the early-career professional, there is an array of sessions to attend — from conquering the boards to building your practice. Here are some of the essential offerings for residents, happening during the AAD Annual Meeting.

Friday, March 25

- C001 - Conquer the Boards: An Experiential Review
- S005 - Gross and Microscopic Symposium

Saturday, March 26

- S024 - Gross and Microscopic Symposium
- U036 - Business Bootcamp for Dermatologists - Surviving and Thriving in the New Era of Medicine
- F039 - Boards and Beyond
- S022 - Resident and Fellows Symposium
- C009 - Basic Self-assessment of Dermatopathology Discussion

Sunday, March 27

- S044 - Boards Blitz
- S049 - Resident Jeopardy
- F084 - Young Physician Pearls and Pitfalls: A Survival Guide for the First 10 Years

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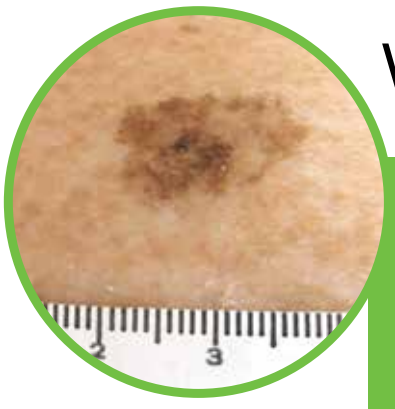

What's new in early-stage melanoma?

Michael E. Ming, MD, FAAD, associate professor of dermatology at the University of Pennsylvania Perelman School of Medicine in Philadelphia.

Caroline C. Kim, MD, FAAD, director of the Melanoma and Pigmented Lesion Programs at Tufts department of dermatology.

Emily Y. Chu, MD, PhD, FAAD, associate professor of dermatology at the University of Pennsylvania.

Susan Swetter, MD, FAAD, professor of dermatology and director of the Pigmented Lesion and Melanoma Program at the Stanford University Medical Center in Stanford, California.

Giorgos Karakousis, MD, associate professor of surgery at the University of Pennsylvania Perelman School of Medicine.

F020 – The Changing Landscape of Early-Stage Melanoma Management
Friday, March 25 | 1 – 3 p.m.
Room: 258C

Management of early-stage melanoma (melanoma confined only to the skin) continues to evolve. Changes and advances in diagnostic techniques and tools are changing the way we think about prevention strategies and treatment plans.

"Melanoma is a condition that comes up every day in a general dermatology practice," said Michael E. Ming, MD, FAAD, associate professor of dermatology at the University of Pennsylvania Perelman School of Medicine in Philadelphia. "Recent changes in the field could affect how we think about early-stage melanoma and how we discuss it with our patients."

Dr. Ming will chair the new forum, **F020 - The Changing Landscape of Early-Stage Melanoma Management**. Attendees can expect the latest on issues such as how to choose appropriate genetic testing for melanoma patients or their relatives, considerations when counseling patients about the use of sunscreens, the role of gene expression profiling, surgical treatment options, and the availability of clinical trials.

Genetic expression profiling at the bedside and improved imaging technology is already moving out of academic centers into dermatology practices nationwide.

Sorting out latest sunscreen data

Today's session will also address some of the current controversies surrounding the use of sunscreen. Some jurisdictions have banned the use of certain common sunscreen ingredients, due to the possibility that they could affect marine life studies. It also has raised the question of potential harm to human users from some ingredients.

"An estimated 14,000 tons of sunscreen washes off humans into the oceans every year," Dr. Ming said. "We will be exploring the data to see whether that poses a theoretical risk to marine life or if there is concrete evidence of harm. And we will discuss the current literature and how to counsel patients about whether there is demonstrable harm to themselves if they use specific ingredients, or if that risk is only theoretical."

New tests and technologies

"As dermatologists, we welcome new technologies to help us diagnose melanoma," said Caroline C. Kim, MD, FAAD, director of the Melanoma and Pigmented Lesion Programs at Tufts department of dermatology. "However, it is important to understand strengths and limitations of these new tests and technologies as well as potential utilization strategies to best serve our patients. Adhesive genetic expression profiling tests, for example, are a currently available, non-invasive testing option for concerning pigmented lesions. Updated imaging technology can have a similar impact on practice."

For many physicians and patients, it can be challenging to keep up with new developments.

"There are more options in technology now to assess genetic variation related to patients' cancers. It can be a little confusing to figure out which test (if any) is more appropriate for which patient at a given time," said Emily Y. Chu, MD, PhD, FAAD, associate professor of dermatology at the University of Pennsylvania.

New molecular testing being employed

Somatic molecular testing is being used to help guide therapeutic decisions in more advanced melanoma, Dr. Chu said. For early-stage disease, molecular tests have been developed that may help distinguish between melanoma and benign lesions that can mimic cutaneous melanoma under the microscope. And growing numbers of patients arrive at appointments with "information" collected online that may — or may not — be relevant or even accurate.

"Having as much valid information as possible is incredibly helpful from the clinician standpoint when you are taking care of patients who are increasingly savvy but may not have all of the information or the context to put it into perspective," Dr. Chu said. "As physicians, we have to be aware of the current genetic and molecular testing options."

The literature is complicated when discussing the value of molecular testing in early-stage disease. The debate is often framed in yes/no statements, but the practical value is more nuanced.

"Key controversies in early-stage melanoma management include utilization of molecular techniques that can aid in melanoma diagnosis and prognosis, particularly various gene expression profiling (GEP) tests," said Susan Swetter, MD, FAAD, professor of dermatology and director of the Pigmented Lesion and Melanoma Program at the Stanford University Medical Center in Stanford, California. "GEP tests may serve an adjunctive role to melanoma stage and other clinopathologic factors that help predict outcome or likelihood of sentinel lymph node biopsy, but they are not yet incorporated into national melanoma guidelines as part of routine care. This session will help explain the current state of molecular testing for melanoma diagnosis and management."

Melanoma and surgery

There are also controversies surrounding surgical approaches to early-stage melanoma. Mohs micrographic surgery and staged excision with permanent sections have been reported as more effective in reducing local recurrence in certain melanoma subtypes, mainly melanomas *in situ* and thin invasive melanomas in chronically sun-exposed areas of the head or on acral sites, which are anatomically constrained. However, prospective data for Mohs surgery or staged excision with permanent sections versus conventional wide excision are lacking when it comes to thicker invasive melanomas.

More emphasis on evidence-based recommendations

"Dermatologists 'own' the field of early melanoma and should be thoroughly up-to-date on current evidence-based recommendations," Dr. Swetter said.

Up-to-date includes the latest drug approvals, including pembrolizumab, which the FDA okayed for Stage II B and C melanoma in late 2021.

"This is a very positive change for patients who are sentinel lymph node negative, but we know are still at high risk for recurrence," explained Giorgos Karakousis, MD, associate professor of surgery at the University of Pennsylvania Perelman School of Medicine.

"At the same time, there are other neoadjuvant therapies that are still in clinical trials that will be discussed. Melanoma is one of the most lethal skin diseases out there, which makes having a good grounding in the new and innovative approaches to early-stage disease all the more important for physicians."

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Tracking malignant melanoma treatment outcomes

Featured speakers:

Ryan Sullivan, MD, associate professor of medicine at Harvard Medical School and of the hematology/oncology department at Massachusetts General Hospital Cancer Center

Nicole R. LeBoeuf, MD, MPH, FAAD, chief of oncodermatology, director of the program for Skin Toxicities for Anticancer Therapy at Dana Farber Cancer Institute, and associate professor of dermatology at Harvard Medical School

S013 – Malignant Melanoma: Molecular Diagnostics, Emerging Therapies, and the Microbiome
Friday, March 25 | 1 – 4 p.m.
Room 151B

Melanoma is becoming a chronic disease for growing numbers of patients. Dermatologists are able to work with oncologists to improve quality of life throughout treatment, and after, as patients live longer.

The approval of ipilimumab for advanced melanoma in 2011 opened a new chapter for managing and treating malignant melanoma. A growing list of new targeted and immune therapies, new combinations, new genetic testing, new classifications, new prognostic factors, and new side effects are transforming melanoma outcomes.

"Malignant melanoma is one of the two or three most dangerous diseases that dermatologists come across," said Ryan Sullivan, MD, associate professor of medicine at Harvard Medical School and of the hematology/oncology department at Massachusetts General Hospital Cancer Center. "The news is not all doom and gloom. We have continued to make progress in melanoma, and there is good hope that many more of our patients will do well."

Dr. Sullivan will discuss the latest findings and treatment approvals in melanoma during today's session, **S013 – Malignant Melanoma: Molecular Diagnostics, Emerging Therapies, and the Microbiome**, led by Martin Charles Mihm Jr., MD, FAAD, along with a panel of other experts who will discuss the latest developments in morphology and molecular pathology of different melanoma subtypes and borderline lesions, new management algorithms and treatment options, growing recognition of interactions between the gut microbiome and response to therapy, and more.

The ultimate message is that melanoma is becoming a chronic disease for growing numbers of patients. As more patients survive longer, quality of life is emerging as a major focus.

New opportunities for the field

"We are seeing patients maintained on their systemic therapies for long periods of time," said Nicole R. LeBoeuf, MD, MPH, FAAD, chief of oncodermatology, director of the program for Skin Toxicities for Anticancer Therapy at Dana Farber Cancer Institute, and associate professor of dermatology at Harvard Medical School. "We are seeing more and more complete remissions in the setting of immune checkpoint inhibitors and more and more regimens using combination anticancer regimens that include immunotherapy. The most challenging thing for patients and medical oncologists, but a wonderful opportunity for our field, is that these immunotherapies may cause any and all dermatologic conditions as part of their side effect profile."

Oncodermatologists joke that immunotherapy "causes dermatology," Dr. LeBoeuf added. In reality, immunotherapy side effects are not limited to the skin.

"The remarkable phenomenon is that across each and every organ system, immunotherapy can and does induce the full spectrum of immune-mediated disease," Dr. LeBoeuf said. "As these treatments have become more and more effective, the study of side effects has also become more important. We want to uncouple the toxicity of the checkpoint inhibitor from its therapeutic effects to allow patients to have not only quantity of life but higher quality of life. The skin is often the earliest and most common organ affected, so medical dermatologists have an important role in leading this charge."

Managing treatment toxicities took on added importance when pembrolizumab was approved for Stage IIB and IIC melanoma in late 2021.

"That approval is going to make a difference in managing patients with Stage II and III disease and which patients to consider for therapy," Dr. Sullivan said. "With a drug available, it is important to make the appropriate referrals to an oncologist and make sure those conversations happen. We could be seeing approval for a new combination in frontline melanoma therapy any day now. He added that the forum will be introducing "new options that are available now, options that are likely to become available in the near future, and how data in the prospective setting can help us select which patients are most appropriate for which approaches."

Genetics, oncology, and melanoma

Genetic testing is an ever more-important option. About half of patients with metastatic melanoma have a BRAF mutation, which makes a crucial difference in selecting therapy.

Genetic testing is already recommended for Stage III or IV melanoma, Dr. Sullivan added, and may inform therapeutic decisions for Stage II disease as well. Tumor genotyping could become as important in managing melanoma as it already is in breast, prostate, lung, and other cancers.

Improved management for malignant melanoma is fostering closer cooperation between oncology and dermatology. Dr. LeBoeuf noted that oncologists are long beyond the point where they should feel compelled to manage all of their treatment side effects.

"Just like primary care physicians lean on specialists to deal with significant immune-mediated diseases, oncologists should lean on them for these diverse immune side effects of treatment," she said. "If a patient comes in with a rash, we know what to look for in a physical exam, the questions to ask about their overall health and what treatments they might be on. We are trained to see the subtle things, the nuances, that other specialties might not notice."

The ideal, Dr. LeBoeuf said, is working cooperatively with oncologists to monitor patients for dermatologic side effects. These close relationships are increasingly important with the earlier stage approvals for melanoma.

"That has been a huge paradigm shift," she explained. "When oncologists know there is a dermatologist they can access, they refer more often and are better at choosing specific regimens to manage side effects. It is on us as a field to make sure we are available to our colleagues in a timely manner and communicate with them. Dermatologists have the specific expertise that can keep people on their cancer therapies, to help them have not only a better quality of life but longevity as well. Melanoma is a disease where we are at the front line from beginning to end." ●

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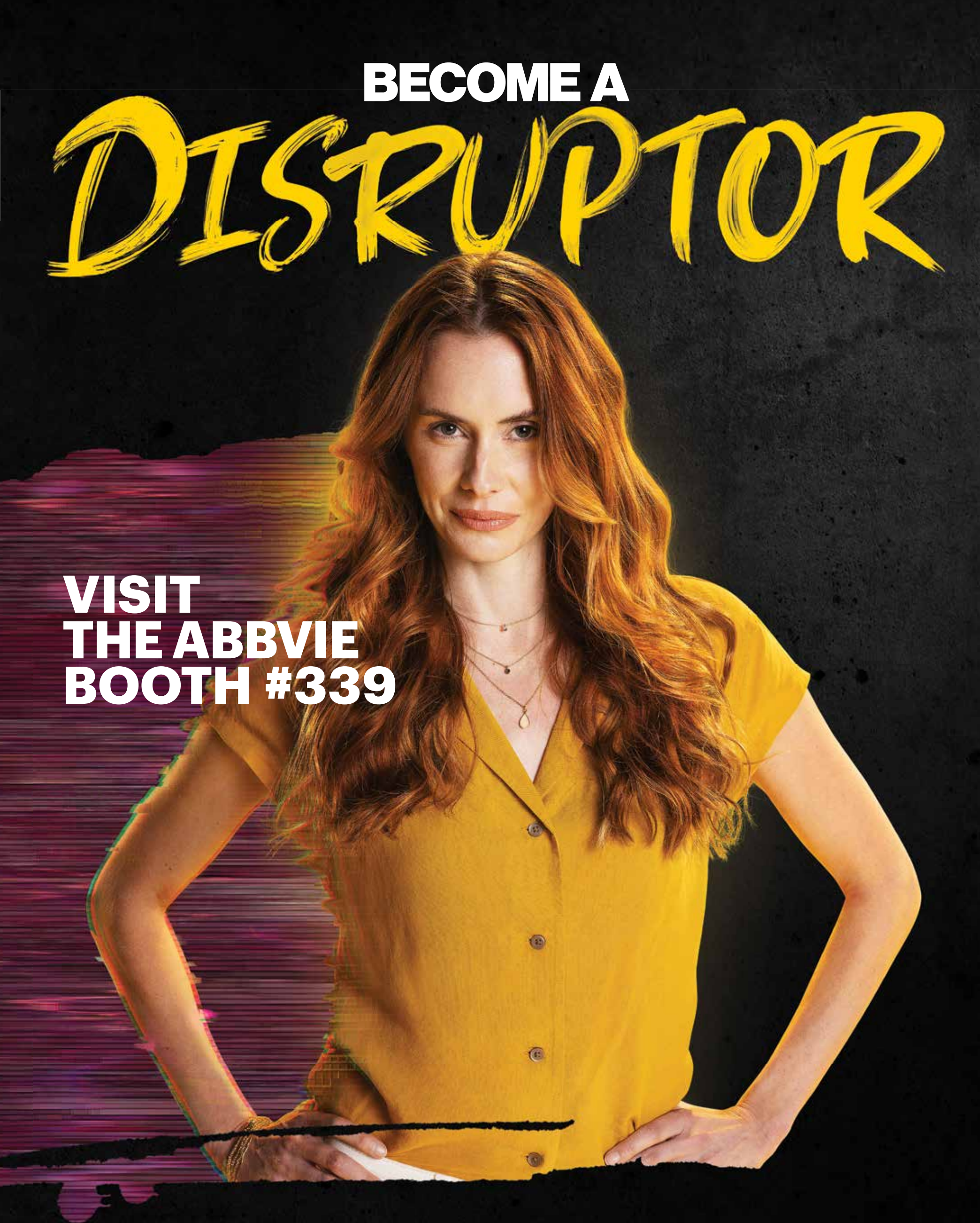

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