Disclosures of relevant relationships with industry

- **Lawrence A. Schachner, MD**
  - **Investigator:** Astellas, Berg Pharma, Celgene, Ferndale Labs, Lilly, Medimetriks, Novartis, Organogenesis Inc., Pfizer, Stiefel Laboratories, Sciton

- **Consultant:** Beiersdorf, Brickell, Cutanea, Hoth, Lexington, Mustela, TopMD
Therapeutic “Arrows in the Quiver”

- Impetigo
- Atopic Dermatitis
- Acne
- Epidermolysis Bullosa
- Hemangiomas
- Alopecia Areata
- Morphea
- Hyperhidrosis
- Molluscum Contagiosum
- Psoriasis

New Therapies in Pediatrics

- First new FDA-approved therapies for atopic dermatitis in 15 years
  - Crisaborole: topical 2016 – 2 years and above
  - Crisaborole: topical 2020 – 3 months and above
  - Dupilumab: systemic 2017 – adults
  - Dupilumab: systemic 2019 – 12 to 17 years
  - Dupilumab: systemic 2020 – 6 years and above

- First new topical antibiotic for impetigo
  - Ozenoxacin: topical 2017

- New FDA-approved oral and topical antibiotics specifically for acne vulgaris
  - Sarecycline: systemic 2018 – 9 years and above
  - Minocycline 4% foam: topical 2019 – 9 years and above
  - Clascoterone 1% Cream: topical 2020 – 12 years and above
  - Trifarotene 0.005% Cream: topical 2019 – 9 years and above

- New FDA-approved treatment for hyperhidrosis (primary axillary)
  - Glycopyrronium cloth: topical anticholinergic 2018 – 9 years and above

- New Treatment for Molluscum Contagiosum
  - 0.7% Cantharidin

Emerging therapies for atopic dermatitis

- Tapinarof 1% cream: topical
- Ruxolitinib cream: topical
- Abrocitinib: systemic
- Upacitinib: systemic
Atopic Dermatitis: Why are new treatments important?

- Atopic dermatitis (AD) is the most common pediatric inflammatory disorder
- Chronic, complex pruritic skin condition associated with significant discomfort, sleepless nights, and stress to the patient and the family
- Recent studies show increased risk of suicide in preteen patients with AD
- Evidence continues to suggest that AD can become a systemic disease → we want to halt the atopic march
- Topical therapy has been the mainstay of treatment in childhood AD...
- Emergence of new targeted topical and systemic therapies should be encouraged

Emerging Therapies in Atopic Dermatitis

Emerging:
- Monoclonal antibodies against IL-13 and 31RA
- Phosphodiesterase-4 inhibitors
- JAK inhibitors
- Transient receptor potential (TRPV1) antagonist
- T-cell inhibitors
- Prostaglandin/leukotriene inhibitors
- Mimics of glutathione peroxidase (Ebselen)
- Antimicrobial peptides (AMPs) such as PXL150
- Aryl hydrocarbon receptor (AhR) modulating agent

1Sandhu J, Wu KK, Bui T, Armstrong AW. Association Between Atopic Dermatitis and Suicidality: A Systemic Review and Meta-analysis. JAMA Dermatology 2018
Crisaborole

- First topical Phosphodiesterase-4 inhibitor (PDE-4)
- U.S. FDA approved for mild-moderate atopic dermatitis
  - 2016: 2 years and older
  - 2020: 3 months and older
- Mechanism of action: inhibition of PDE-4 → increase intracellular cAMP levels → suppresses the release of pro-inflammatory cytokines
- Offers alternative to long-term steroid use
- Crisaborole ointment 2% applied twice daily

Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults

- Two identically designed multicenter, randomized, double-blind, vehicle-controlled phase III

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>AD-301 (p=0.038)</th>
<th>AD-302 (p&lt;0.001)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crisaborole (N=503)</td>
<td>Vehicle (N=256)</td>
</tr>
<tr>
<td>Success in ISGA</td>
<td>32.8%</td>
<td>25.4%</td>
</tr>
</tbody>
</table>

*ISGA: Investigator’s static Global Assessment score*

- More crisaborole-treated patients achieved improvement in ISGA score at day 29 and achieved earlier success than those treated with vehicle ointment

Efficacy and safety of crisaborole ointment continued...

- Improved disease severity by decreasing pruritus, erythema, exudation and lichenification at day 29\(^1\)

- Pruritus improvement noted as early as day 8 (58 vs 42%, p<0.001)\(^1\)

- Safety end point:
  - A 48-week, phase 3 trial studied the long-term safety of crisaborole ointment and showed a low frequency of adverse events\(^2\)
  - Most common was URI (10.3%), flare/worsening of atopic dermatitis (11.2%)\(^2\)
  - 93.1% of AEs deemed unrelated to crisaborole treatment\(^2\)


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Crisaborole’s role on the Schachner Steroid Ladder:

<table>
<thead>
<tr>
<th>Severity</th>
<th>Topical Treatment</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Severe</td>
<td>Clobetasol (high potency CS) + TCI or PDI + emollients</td>
<td>Twice daily for 3-5 days</td>
</tr>
<tr>
<td>If Moderate</td>
<td>Triamcinolone (medium potency CS) + TCI or PDI + emollients</td>
<td>Twice daily for 3-5 days</td>
</tr>
<tr>
<td>If Mild</td>
<td>Alclometasone (low potency CS) + TCI or PDI + emollients</td>
<td>Twice daily for 3-5 days</td>
</tr>
<tr>
<td>Controlled</td>
<td>TCI or PDI or TS + emollients</td>
<td>Twice daily for 2 weeks</td>
</tr>
<tr>
<td>Maintenance (to areas of predilection):</td>
<td>TCI or PDI or TS + emollients</td>
<td>Twice weekly for 6 months</td>
</tr>
<tr>
<td>Long-term Maintenance &amp; Prevention:</td>
<td>Emollients</td>
<td>Twice daily</td>
</tr>
</tbody>
</table>

* Abbreviations: CS: Corticosteroid, PDI: Phosphodiesterase inhibitor, TCI: Topical Calcineurin Inhibitor

PDI application site pain: frequency and clinical relevance

- There are reports of application site pain, described as a “burning or stinging” sensation.\(^1,4\)
- Randomized controlled clinical trial (RCT) conducted in Australia on adults resulted in 4% of subjects experiencing pain.\(^3\)
- RCTs from the US found a frequency of 4.4% in children.\(^2\)
- A 48 week extension study was conducted in which the incidence of pain was 2.3% of patients and noted to decrease over time.\(^4\)
- A retrospective study conducted at Tufts Medical Center in adults found a frequency of 31.7%.\(^2\)

Clinical relevance:
- May decrease patient compliance and use in AD
- Efficacy without stinging in intertriginal and facial psoriasis in adults: difference in barrier function may explain the total lack of application site reaction.\(^5\)

Mitigation Strategies and Impact Reduction Strategies

- Goal is to enable improved compliance
- Potential strategies
  - Begin TCS for 3 days before adding PDI to treatment regimen
  - Can utilize a slow introduction approach (e.g. TCS or emollient and PDI together in a 5:1 ratio and titrate
  - Very thin application with or without TCS or emollient
  - Can cool the PDI by placing in refrigerator at 2 - 8°C
  - Modify formulation

References:
Dupilumab

Dupilumab is an immune modulating biologic treatment of **moderate to severe** atopic dermatitis (AD)

- It is a fully human monoclonal antibody directed against the shared alpha subunit of the IL-4 receptor resulting in signaling blockade of IL-4 and IL-13, which are key drivers of Th2-mediated inflammation of AD

- Suppresses the expression of genes related to the activation of Th2 cells and related inflammatory pathways, a major driver in AD clinical disease

- Currently approved in children **12 years and older**

- Studies now ongoing starting from **6 months of age**

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**Dupilumab continued...**

**Dosing**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Weight Range</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-17 years</td>
<td>15-29 kg</td>
<td>600 mg loading dose + 300 mg every 4 weeks</td>
</tr>
<tr>
<td></td>
<td>30-59 kg</td>
<td>400 mg loading dose + 200 mg every other week</td>
</tr>
<tr>
<td></td>
<td>60 kg or more</td>
<td>600 mg loading dose + 300 mg every other week</td>
</tr>
<tr>
<td>18+ years</td>
<td>600 mg loading dose + 300 mg every other week</td>
<td></td>
</tr>
</tbody>
</table>

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*DupireneTM* Dosing and Administration, [https://www.dupirenehcp.com/atopicdermatitis/dosing-administration](https://www.dupirenehcp.com/atopicdermatitis/dosing-administration)
Current clinical trials and possible future indications for Dupilumab

Indications:

- **Moderate to severe AD** not responding to topical treatment (as monotherapy or in combination with topical steroids)
  - *Also reports of efficacy in severe palmoplantar dyshidrotic eczema*¹
- **Moderate to severe asthma** (approved 2018)
- Dupilumab is currently undergoing a phase 3 trial for the treatment of AD in children > 6 months to 18 years old
- An open label multicenter extension study revealed a favorable long-term (> 1 year) safety and efficacy profile in adults²
- 24 children < 11 yo with efficacy (IGA and EASI scores were not as striking as adults)³
  - *Pediatric metabolism*

¹Nanda S, Nagrani N, Macquhae F, Nichols A. Case of Complete Resolution of Severe Plantar Dyshidrotic Eczema with Dupilumab. JDD 2018; 18(2)

Safety and Efficacy Studies

- Deleuran et al. recently conducted an open label multicenter extension study to determine long-term (76 weeks) safety and efficacy profile in adults
  - Loading dose of 600 mg with 300 mg maintenance dose given weekly
  - Overall, there were 420 adverse events (AEs) per 100 person-years (PYs) and 8.5 serious AEs per 100 PYs
  - Most AEs were mild to moderate and most commonly included nasopharyngitis, upper respiratory tract infections, AD, and headache
  - Injection site reactions and conjunctivitis-related side effects diminished in incidence over time
  - Only 1.8% of patients overall discontinued the study before data cutoff
  - By week 76, most patients showed significant improvement in pruritus, quality of life, and AD disease activity

Emerging Topical Therapies

■ Tapinarof 1% cream
  - Therapeutic aryl hydrocarbon receptor (AhR) modulating agent
  - Phase II trial showed treatment success in 53% when applied twice daily (children and adults)\(^1\)

■ Ruxolitinib cream
  - JAK1/2 inhibitor
  - Phase II trial showed 71.6% improvement from baseline in EASI score at 4 weeks with 1.5% concentration applied BID in adults\(^2\)


Abrocitinib: Jak-1 inhibition

■ Granted breakthrough therapy designation from the FDA in February 2018 after significantly alleviating IGA and EASI scores in adults in phase II and phase III RCTs

■ Phase III trial of abrocitinib in adolescents and adults 12 years or older with moderate-to-severe AD
  - JADE MONO-1 & JADE MONO-2: abrocitinib 200- or 100mg resulted in significant reductions in IGA, EASI, and PP-NRS scores compared with placebo

■ Preliminary results of phase III trial of abrocitinib in adolescents aged 12-18 years (JADE TEEN, NCT03796676) yielded similar results

Simpson et al. European Academy of Dermatology and Venereology 28th Congress 2018
Silverberg et al. JAMA Derm 2020.
Upadacitinib: Jak-1 inhibition

- Phase III data of 15- or 30mg upadacitinib monotherapy meeting all primary endpoints (IGA, EASI-5) in adults with moderate-to-severe AD
- Granted breakthrough therapy designation by the FDA in January 2018
- Phase III trials currently ongoing for the use of upadacitinib in adolescents and adults over the age of 12 with moderate-to-severe AD (NCT03661138, NCT03568318)
- Phase I study for pediatric patients aged 6 months to 12 years of age with severe AD is currently in recruitment (NCT03646604)


IMPETIGO

- Impetigo is **THE MOST** frequent bacterial skin infection seen in pediatrician’s office.
- Impetiginized dermatosis is a leading issue in the Dermatology office.
- Emergence of resistance to mupirocin, retapamulin, bacitracin, fusidic acid, and virtually all other topical antibiotics have been noted...
- The last new topical antibiotic approved was 11 years ago (April 2007)
- ...Therefore, there is a great need for new topical antibiotics!
Ozenoxacin for Impetigo

12/11/2017 FDA approves Ozenoxacin for topical treatment of impetigo
- Non-fluorinated quinolone
- Children 2 months or older
- Mechanisms of action:
  a) Blocks DNA gyrase
  b) Blocks topoisomerase IV enzymes
  c) Spectrum includes S. aureus, S. Pyogenes, and MRSA

Before Ozenoxacin in December 2017, the last topical antibiotic approved was Retapamulin 12 years ago (April 2007)!

Ozenoxacin Clinical Development

- Ozenoxacin cream 1% was developed for the first-line treatment of impetigo in patients aged 2 months and older and has been studied in 17 clinical trials to date
  - 15 clinical studies in Phase 1 and 2 have been conducted
  - 2 Pivotal Phase 3 studies in both adult and pediatric patients with impetigo 2 months and up have been completed.

- Patients were treated BID for 5 days
- Ozenoxacin demonstrated superior clinical and bacteriologic outcomes vs. matching vehicle control
Ozenoxacin: The New Player

- Ozenoxacin demonstrated superior clinical and microbiological success in pediatric patients, as young as 2 months of age, and adults with impetigo in two large studies.
- Effective against S. aureus; S. pyogenes; MRSA; Mupirocin RSA, & Ciprofloxacin RSA
  - Increased resistance to mupirocin creates a need and opportunity for new topical antibiotics for impetigo & impetiginized skin disorders:
    - NYC 2015, 31.3% S aureus resistant to mupirocin in a pediatric population
    - Houston 2018, ~10% of STIs resistant to both Retapamulin and Mupirocin
- Ozenoxacin had faster microbiological success than Retapamulin.
  - Could lead to a more rapid resolution of infectivity in individual and contacts


Before and After Ozenoxacin: In Clinical Practice

A 3 year-old atopic with secondary impetiginization and early furunculosis placed on Cephalexin and Ozenoxacin... but did not take Cephalexin.

Day 1

Day 5
Before and After Ozenoxacin: In Clinical Practice

Day 1 | Day 5

Before and After Ozenoxacin: In Clinical Practice

Day 1 | Day 3
Before and After Ozenoxacin: In Clinical Practice

A 4 year old atopic with an impetiginized ear infection was started on Xepi

Day 1  Day 3  Day 5

Ozenoxacin: Considerations

- Ozenoxacin is typically well-tolerated: no irritation, photo irritation, sensitization or photo allergy

- Out of 206 patients:
  - 0 patients had a serious adverse event
  - 1 adult patient out of 260 reported seborrheic dermatitis and rosacea

ACNE VULGARIS

- Acne vulgaris is one of the most common skin conditions in children and adolescents, affecting up to 93% of adolescents.

- The mainstay of acne treatment includes topical gels and/or antibiotics, off-label use of oral antibiotics, hormonal medications for females, or oral isotretinoin for moderate to severe or refractory cases.

- Great need for new oral and topical antibiotics specifically targeting acne vulgaris.


Sarecycline for moderate to severe acne vulgaris

- NEW tetracycline-class oral antibiotic for acne that target cutaneous *P. acnes* but LOW activity against healthy gram-negative gut bacteria.

- FDA-approved for non-nodular moderate to severe acne on October 2018.

- Once-daily dosage at 1.5 mg/kg/day.

- Safe and effective in children 9 years and older.

- Highly active against *C. acnes* strains, *S. epidermidis*, and *S. aureus*.


Low levels of mutation frequency and antimicrobial resistance

- Narrow antibacterial spectrum with limited activity against enteric gram-negative bacteria (ie Enterococcus faecalis, E. Coli, Klebsiella, Proteus) leading to greater preservation of natural gut microbiota compared with other tetracycline antibiotics

- Low spontaneous mutation frequencies for C.acnes, S. Aureus, and S. epidermidis

C7 and C9 positions were changed to create a tetracycline derivative to overcome resistance mechanisms

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Sarecycline: Clinical Development

- One phase 2 and three phase 3 clinical trials have been conducted studying the safety and efficacy of Sarecycline in the treatment of acne vulgaris

- Two identically designed multicenter, randomized, double-blind, vehicle-controlled phase 3 conducted in the US

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Figure 1. Study design for SC1401 and SC1402. IGA, Investigator’s Global Assessment. *After enrollment began, a protocol amendment removed the lower limit for noninflammatory lesion count at baseline.

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Moore A, Green L, et al. Once-Daily Oral Sarecycline 1.5 mg/kg/day Is Effective for Moderate to Severe Acne Vulgaris: Results from Two Identically Designed, Phase 3, Randomized, Double-Blind Clinical Trials. Journal of Drugs and Dermatology. 2018;17(9):987-996.
Outcomes of the Sarecycline Studies

- 1.5 mg/kg Sarecycline daily significantly reduced inflammatory acne lesions compared to placebo
  - Specifically, active treatment group demonstrated a statistically significant, 52% decrease in inflammatory lesions at week 12, compared with a 38% decrease in placebo\(^1\)
  - 22% of patients had grade 0 (clear) or 1 (almost clear) compared to 10% in the placebo group\(^2\)

- Higher dosing (3.0 mg/kg) did not have significantly higher efficacy than the 1.5 mg/kg daily

- Very low rates of adverse events, including gastrointestinal side effects

\(^1\)Leyden JJ, Sniukiene V, Berk DR, Kasukhov A. Efficacy and Safety of Sarecycline, a Novel, Once-Daily, Narrow Spectrum Antibiotic for the Treatment of Moderate to Severe Facial Acne Vulgaris: Results of a Phase 2, Dose-Ranging Study. J Drugs Dermatol. 2018;17:333-8
\(^2\)Moore A, Green L, et al. Once-Daily Oral Sarecycline 1.5 mg/kg/day Is Effective for Moderate to Severe Acne Vulgaris: Results from Two Identically Designed, Phase 3, Randomized, Double-Blind Clinical Trials. Journal of Drugs and Dermatology. 2018;17(9): 987-996.

Safety and Adverse Effects of Sarecycline

- SAFE and WELL-TOLERATED\(^3\)

- Recommended dosing
  - 33 - 54 kg: 60 mg daily
  - 55 - 84 kg: 100 mg daily
  - 85 - 136 kg: 150mg daily

- We are continuing to uncover more about the importance of a healthy microbiome & preserving natural flora → sarecycline has limited activity on gut bacteria

- Unlike doxycycline, sarecycline is associated with very low rates of GI side effects (nausea in 4.6%, vomiting in 2.1%, diarrhea rates ~ placebo)

- Compared with minocycline, sarecycline is NOT associated with vestibular symptoms such as dizziness, tinnitus, or vertigo (< 1% of patients on sarecycline experience these side effects)

- Did not cross the blood-brain-barrier in infant mammal studies

Moore A, Green L, et al. Once-Daily Oral Sarecycline 1.5 mg/kg/day Is Effective for Moderate to Severe Acne Vulgaris: Results from Two Identically Designed, Phase 3, Randomized, Double-Blind Clinical Trials. Journal of Drugs and Dermatology. 2018;17(9): 987-996.
Minocycline 4% topical foam

- Minocycline foam received **FDA-approval** October 2019 for the treatment of non-nodular moderate-to-severe acne vulgaris in adults and pediatric patients at least 9 years old
  - Commercially available to prescribe as of January 13th, 2020!
- Tetracyclines can lead to photosensitivity → must warn patients about the danger of sun exposure while using this product
- The global alliance on acne always recommends benzoyl peroxide be started with any topical antibiotic therapy

Should be applied to the skin once daily, at least 1 hour before bedtime

- Minocycline foam was found to have significantly better results than vehicle in multiple phase 2 and 3 studies
- Significant reduction in inflammatory lesions compared to vehicle
- Higher treatment success according to the Investigator’s Global Assessment
- Should minimize systemic adverse effects of oral minocycline

**Clascoterene Cream, 1%**

- First topical androgen receptor inhibitor
- FDA-approved in August 2020 for acne vulgaris in ages 12+
- Unlike systemic anti-androgens, may be used in males as well as females
  - Drug is metabolized to cortexolone (inactive), limiting systemic absorption
- Application is 1g twice per day

**Mechanism of Action**

- DHT typically binds androgen receptor in sebocytes
  - This promotes the production of sebum and inflammatory cytokines
- Clascoterone blocks DHT by competitively binding to the androgen receptor
  - Drug therefore affects multiple acnegenic pathways

Evidence

- Two identically-designed Phase 3 trials showed statistically significant superior treatment success rates in clascoterone group compared to vehicle (18.4% v 9.0% and 20.3% v 6.5%)
  - Treatment success defined as 2-point reduction in IGA score from baseline and a score of 0-1 at 12 weeks
- 9-month extension study with participants from Phase 3 clinical trials revealed few adverse effects
- Pilot study with adult male participants suggested clascoterene may be more clinically effective than tretinoin 0.05% cream (although not statistically significant)


Trifarotene 0.005%

- First fourth-generation retinoid (selective RAR-ϒ agonist)
- FDA-approved for acne vulgaris in ages 9+ since 2019
- Orphan drug status given in 2014 for congenital ichthyosis
  - Selective nature allows for half life in hepatic microsomes of 5 minutes, permitting safe application on large areas

Evidence

- Two identically-designed Phase 3 studies reported statistically-significant differences in success rates when compared to vehicle at 12 weeks
  - Face: 29.4% v 19.5% and 42.3% v 25.7%
  - Trunk: 35.7% v 25% and 42.6% v 29.9%
  - Reduced lesions seen as early as week 1 for the face and week 2 for the trunk

- Longer-term Phase 3 study showed success rates at 52 weeks as 65.1% for the face and 66.9% for the trunk

- Cutaneous adverse effects in 12.6%, most commonly pruritus, irritation, and sunburn

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Hyperhidrosis

- Hyperhidrosis (HH) is a disorder of the eccrine sweat glands
- Affects about 3% of people in the world
  - Likely higher in the pediatric population because it is underreported and underdiagnosed
- Negatively impacts quality of life
  - Provokes anxiety, embarrassment, and social isolation which can be especially detrimental for emotional development of children
- Frequently involves the axillae, palms/soles, face, scalp, inframammary regions, and groin
  - Children with palmoplantar involvement may show signs as early as toddler years

• HH can be primary (idiopathic) or secondary (pathologic)
  • May be further subdivided into focal or generalized forms

• Underlying mechanism is unknown, but current theory attributes the disorder to a hyperfunction of eccrine glands

• Primary HH is more commonly observed
  • Excessive sweating is symmetric typically involving the soles, palms, and/or axillae
  • Usually a family history is present
  • May begin around puberty
  • Diagnosis is made through history and physical exam


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**Anticholinergics: Most Common Oral Medications**

- Maximum efficacy may be observed as soon as 1 week after initiating use of oral anticholinergic agents
- **Glycopyrrolate is most frequently used** due to its diminished ability to cross the blood-brain barrier (BBB)
  - Recommended to give 40–100 mcg/kg/dose; twice daily dosing is often enough to control symptoms but may be given up to 4x per day
  - A retrospective study by Paller et al. found that 90% of pediatric patients showed improvement at a mean dosage of 2 mg per day
- Oxybutynin is the next most commonly used but easily crosses the BBB
  - For children > 5 years old, may begin at 2.5 mg daily and gradually increase to 15 mg daily
  - For children < 5 years old, 5 mg/5 mL suspension should be dosed at 0.1 mg/kg/dose and may be given up to three times per day

Oral Anticholinergics: Adverse Effects May Impede Usage

- Efficacy is typically achieved at dosages that induce side effects (dry mouth, blurred vision, dry eyes, urinary retention)
- **One-third** of patients discontinue use due to side effects
- **Gradually** increasing the dosage may help reduce adverse effects
- **Overheating when outdoors is of particular concern in children**


What’s New in the Treatment of HH?

- Newly FDA approved (June 2018) **topical glycopyrronium (Qbrexza®)** for primary axillary HH in adults and children 9 years or greater
  - Consists of a cloth soaked in glycopyrronium
  - Recommended to use 1 cloth to wipe each armpit once daily

What’s in the Pipeline?

- **Sofpironium Bromide** is another new topical anticholinergic for axillary HH that shows promise
  - Favorable phase II results and multiple ongoing phase III clinical trials are planned
  - **Not yet FDA-approved**
Molluscum Contagiosum

- Affects 6 million Americans with 1 million diagnosed every year
- No FDA approved treatments to date*
- Molluscum contagiosum virus (MCV) carries its own RNA polymerase allowing for independent replication
  - MCV-1 predominant in children, MCV-II in HIV patients
  - Incubation period is 2 – 8 weeks
- Carries physical and psychosocial burden
  - Greater number of lesions ➔ greater impact on quality of life
  - Leads to teasing, embarrassment, social isolation
  - Exclusion from school activities or sports
- Those with with AD, in addition to a family history of MC, are especially at risk

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New Treatment for Molluscum Contagiosum

- 0.7% Cantharidin in a film-forming solution (VP-102)
- Single-use drug delivery application device used every 21 days
- Phase III trials in 2 year-olds and up (50% on active had AD)
  - Primary endpoint complete clearance at day 84
  - 50% of active versus 15% of vehicle (p<0.001)
### Summary of New & Emerging Medications

#### New:
1. Crisaborole: topical 2016 (AD)
2. Dupilumab: systemic 2017 (AD)
3. Ozenoxacin: topical 2017 (IMPETIGO)
4. Sarecycline: systemic 2018 (ACNE)
5. Minocycline foam: topical 2019 (ACNE)
6. Clascoterone 1% Cream: topical 2020 (ACNE)
7. Trifarotene 0.005% Cream: topical 2019 (ACNE)
8. Glycopyrronium cloth: topical 2018 (HH)

#### Emerging therapies for atopic dermatitis:
- Monoclonal antibodies against IL-13 and 31RA
- Phosphodiesterase-4 inhibitors
- JAK inhibitors
- Transient receptor potential (TRPV1) antagonist
- T-cell inhibitors
- Prostaglandin/leukotriene inhibitors
- Mimics of glutathione peroxidase (Ebseren)
- Antimicrobial peptides (AMPs) such as PXL150
- Aryl hydrocarbon receptor (AhR) modulating agent