ATOPIC DERMATITIS PEER-TO-PEER EDUCATIONAL TOOLKIT

A compilation of key content from select presentations at the 2021 South Beach Symposium Part I: Medical Dermatology Summit and the Masters of Pediatric Dermatology

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MASTERS OF PEDIATRIC DERMATOLOGY

Clinical Assessment Tools

Validated Sign & Symptom Scoring Tools	Mild	Moderate	Severe
EASI	1.1-7	7.1-21	21.1-50 50.1-72 (very severe)
POEM	3-7	8-16	17-24 25-28 (very severe)
PO-SCORAD	<25	>25 to <50	>50
SCORAD	<25	>25 to <50	>50
Other Tools	**Scoring**		
DLQI – validated questionnaire on the impact of AD on QoL	Each question 0 (not at all) to 3 (very much)		
Pruritus (itch) score – patient's subjective assessment of itch	VAS from 0 (none) to 10 (severe)		

Dr. Peter Lio

Racial Disparities in Atopic Dermatitis

- AD disproportionally affects Black children
- Among US children, more likely to suffer from AD and more likely to seek medical care for AD
- More disfiguring in SOC patients (hypo/hyper-pigmentation)
- Challenges in diagnosing and treating in pediatric SOC patients

Kim Y, et.al. Racial/ethnic differences in incidence and persistence of childhood atopic dermatitis. J Invest Dermatol. 2019 Apr:139(4):827-834
Delzell, E. Everything you need to know about eczema in skin of color. National Eczema Association 2020

Dr. Latanya Benjamin

Associated Comorbidities

- Cochrane systemic review and meta-analysis
- Patients with **vitiligo and alopecia areata** had SS greater odds of atopic dermatitis than control patients, $p < .001$

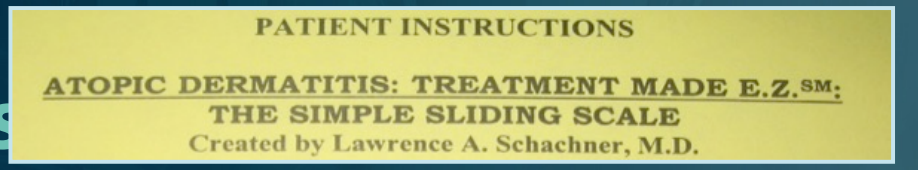
- Recent literature discussed morbidity
  - E.g. **Obesity** and increased **blood pressure** in atopic dermatitis children

- 2018 study discussed **suicidality** in pediatric patients:
  - Korean children with AD were at a significantly higher risk of suicidal ideation (OR 1.23, 95% CI 1.13-.135)
  - Female pediatric patients with AD also had an increased risk of suicidal ideation (adjusted OR, 1.114; 95% CI, 1.046-1.186) and suicide attempts (adjusted OR, 1.188; 95% CI, 1.065-1.325) compared with healthy controls

Mohan G.C and Silverberg J. JAMA Dermatology 2015(5) 522-528
Sandhu J, Wu KK, Bui T, Armstrong AW. JAMA Dermatology 2018

Dr. Lawrence Schachner

At Home Interventions


PATIENT INSTRUCTIONS

ATOPIC DERMATITIS: TREATMENT MADE E.Z.SM:
THE SIMPLE SLIDING SCALE
Created by Lawrence A. Schachner, M.D.

- Basic Rules:
  - Short nails, short bath (3 minutes), cotton clothing, and cool environment
  - Laundry: Hypoallergenic detergent with no bleach or fabric softener.

- Bath Care:
  - If previous Staph infection, use antibacterial soap from the neck down (do not use on face) for three minutes before bath
  - If history of Staph infections, ¼ cup of bleach in 1 ft of water; bleach in a bottle
  - After bath, pat dry. Do not rub!
  - Emollient to ENTIRE body.

Fisher RG, et al. Hypochlorite Killing of CMRSA. Pediatr Infect Dis J. 2008 Oct; 27(10) 934-5.

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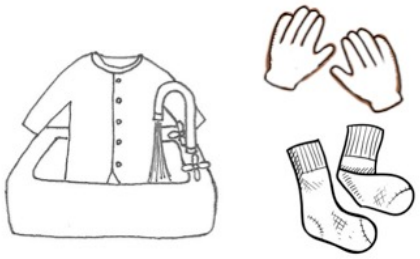
Wet Wraps

Follow these 4 steps:

1. Take one pair of onesies, pajamas, gloves, and/or socks and soak it in warm water.



2. Wring out the onesies, pajamas, glov socks until they are only slightly dam

3. Put the damp onesies, pajamas, gloves, or socks on. Then put the dry onesies, pajamas, gloves, or socks on top of the damp layer.

4. Make sure the room is warm enough go to sleep.

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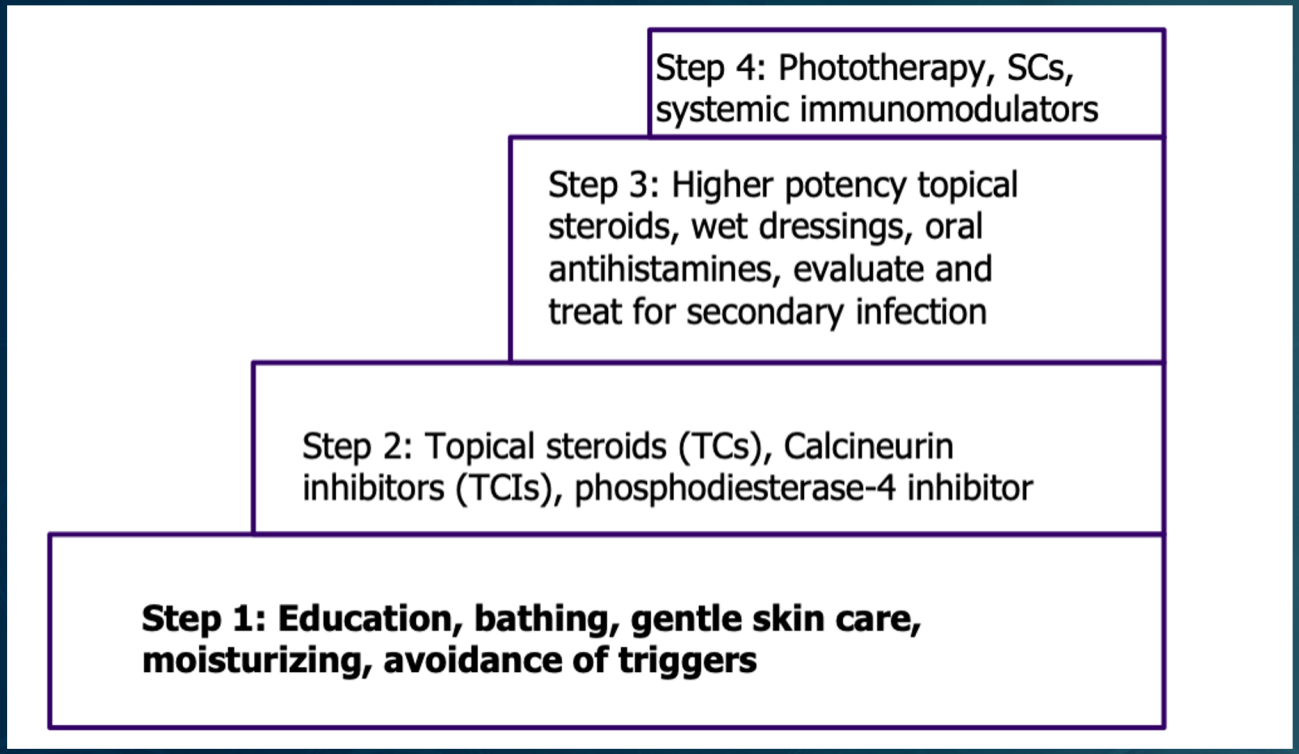
Treatment Recommendations

Pediatric

Adult

Stepwise Treatment Overview for Pediatric Patients



Dr. Latanya Benjamin

Atopic Dermatitis "Treatment Made EZ℠"

The Simple Sliding Scale For Mild to Moderate AD

- Morning:
  - **Emollient to entire body**, even if no inflammation (nothing pink or red).
  - AND
  - Medium strength topical steroid and/or Topical Calcineurin Inhibitors (TCI) and/or Phosphodiesterase inhibitors (PDI) to red areas on body.
  - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to slightly red or pink areas on body.
  - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to pink or red areas on face, groin, and armpits.

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Atopic Dermatitis "Treatment Made EZ℠"

The Simple Sliding Scale For Mild to Moderate AD

- Afternoon: Emollient to all skin.
- Evening:
  - **<u>Emollient to entire body</u>**, even if no inflammation (nothing pink or red).
  - AND
  - Medium strength topical steroid and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to red areas on body (**emollient to other areas**).
  - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to slightly red or pink areas on body (**emollient to other areas**).
  - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to pink or red areas on face, groin, and armpits (**emollient to other areas**)

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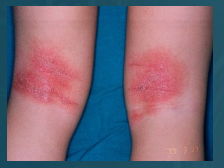
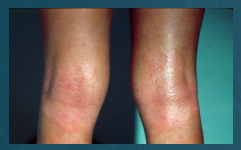
The Schachner Ladder

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





* Antihistamines as needed
* Antibiotics as needed

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

Oberlin KE, Nanda S. Atopic dermatitis made easy: The Schachner Ladder. Pediatr Dermatol. 2019;36(6):1017-8.

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Algorithm For The Treatment Of Moderate To Severe Atopic Dermatitis

- If successful:
  - Titrate down
  - TCI's 2x a week or role for PDI or topical steroid
  - Emollients only

- If unsuccessful:
  1) Patch testing
  2) Narrowband UVB
  3) ***DUPILUMAB***
  4) Class I-II topical steroids
  5) Prednisone
  6) IVPS
  7) UVA, UVB
  8) Cytotoxic and Biologic agents: cyclosporine, mycophenolic acid, cyclophosphamide, azathioprine, methotrexate
  9) INF α or γ subcutaneously
  10) IVIG
  11) Relaxation / Massage therapy / Behavioral/ Probiotics

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Prednisone My Way

- Example – 20 kg child with severe atopic dermatitis

- 1mg/kg/day x 4 days = 20 mg/day
- .75 mg/kg/day x 4 days = 15 mg/day
- .50 mg/kg/day x 4 days = 10 mg/day
- .25 mg/kg/day x 4 days = 5 mg/day

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Cyclosporine My Way

1. Check blood pressure, BUN, Creatinine pre-treatment and each month.

2. Cyclosporine

5mg/kg/day - First Month

4mg/kg/day - Second Month

3mg/kg/day - Third Month

2mg/kg/day - Fourth Month

1mg/kg/day - Fifth Month

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Moderate-to-Severe AD Action Plan

When Flaring (Itchy, Red, Oozing):

AM:
1. Apply fluocinonide to the eczema areas
2. Apply moisturizer liberally
3. Take Vitamin D supplement

PM:
1. Wash with Oil Cleanser
2. Apply fluocinonide to the eczema areas
3. Apply moisturizer liberally
4. Apply damp layer then dry layer (“wet wrap”)

****Do this for several days (up to 1 week) until better…****

Once Better:

AM:
1. Apply crisaborole ointment to remaining areas/trouble spots
2. Apply moisturizer liberally
3. Take Vitamin D supplement

PM:
1. Wash with Oil Cleanser
1. Apply crisaborole ointment to remaining areas/trouble spots
3. Apply moisturizer liberally

Dr. Peter Lio

Moderate-to-Severe AD Action Plan

When Flaring (Itchy, Red, Oozing):

AM:
1. Apply mometasone to the eczema areas
2. Apply moisturizer liberally
3. Take Vitamin D supplement + Probiotic

PM:
1. Wash with Oil Cleanser
2. Apply mometasone to the eczema areas
3. Apply moisturizer liberally

****Do this for several days (up to 1 week) until better...****

Once Better:

AM:
1. Apply tacrolimus ointment to remaining areas/trouble spots
2. Apply moisturizer liberally
3. Take Vitamin D supplement + Probiotic

PM:
1. Wash with Oil Cleanser
1. Apply tacrolimus ointment to remaining areas/trouble spots
3. Apply moisturizer liberally

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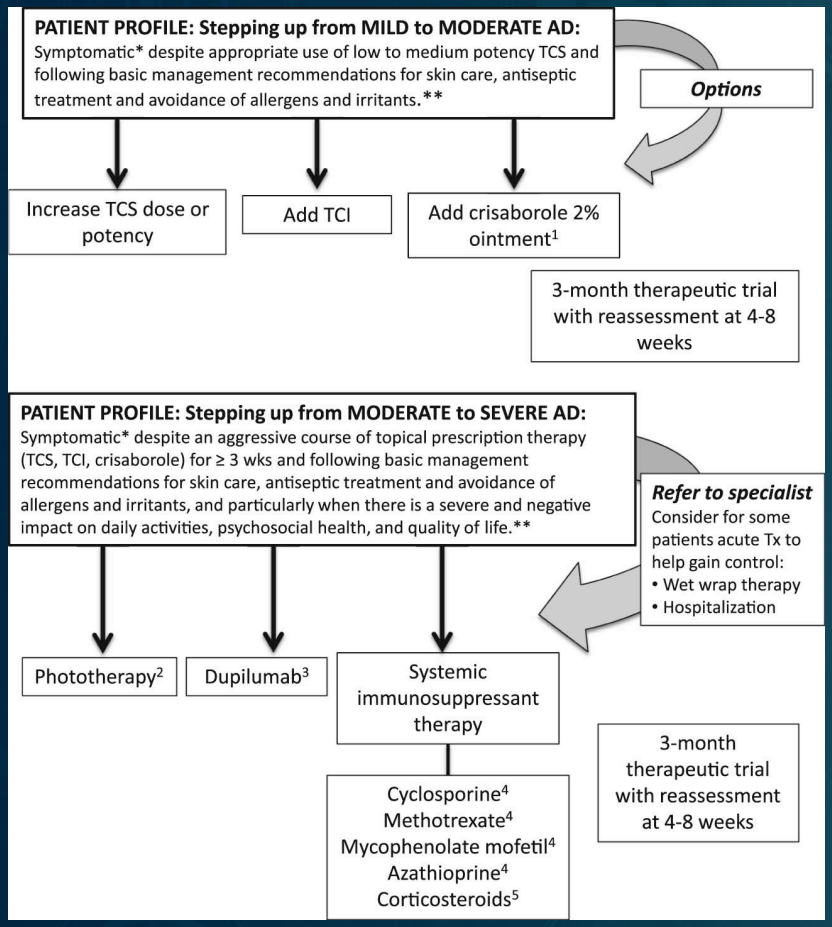

Mark Boguniewicz, MD, Luz Fonacier, MD, Emma Guttman-Yassky, MD, PhD, Peck Y. Ong, MD, Jonathan Silverberg, MD, PhD, MPH, Judith Rosen Farrar, PhD. Annals of Allergy, Asthma & Immunology 2018 120, 10-22.e2DOI: (10.1016/j.anai.2017.10.039)

Dr. Peter Lio

Crisaborole

- First topical Phosphodiesterase 4 inhibitor (PDE-4)
- U.S. FDA approved in December 2016 for mild-moderate atopic dermatitis in patients 2 years of age and older
- Mechanism of action: by inhibition PDE-4, results in increase intracellular cAMP levels which is suppression the release of pro-inflammatory cytokines
- Crisaborole ointment 2% apply twice daily supplies in 60 g and 100 g tube.
- **FDA approved down to 3 months, 2020**

EUCRISA™ (crisaborole) Prescribing Information. New York. NY: Pfizer Inc: 2016

J Pharmacol Exp Ther. 2001;299:753-759

Inflamm Allergy Drug Targets 2007 Mar;6(1):17-26.

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Dupilumab

- Dose: 300 mg subq/ 200 mg subq…60 kg
- Dupilumab comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose (600mg). It can be used with or without topical corticosteroids.
- New dosages for 6-year-olds and up

6-17 years	**15-29 kg**	**600 mg loading dose + 300 mg every 4 weeks**
	30-59 kg	400 mg loading dose + 200 mg every other week
	60 kg or more	600 mg loading dose + 300 mg every other week
18+ years		600 mg loading dose + 300 mg every other week

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Dupilumab

- **Dupilumab** is a successful currently available biologic treatment of a 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

- Indications:
  - Moderate to severe AD not responding to topical treatment (as monotherapy or in combination with topical steroids) in 12 years and up.
  - Now approved 6 years old and up (2020)
  - Current studies are being conducted in 6 month – 6-year-old patients with AD

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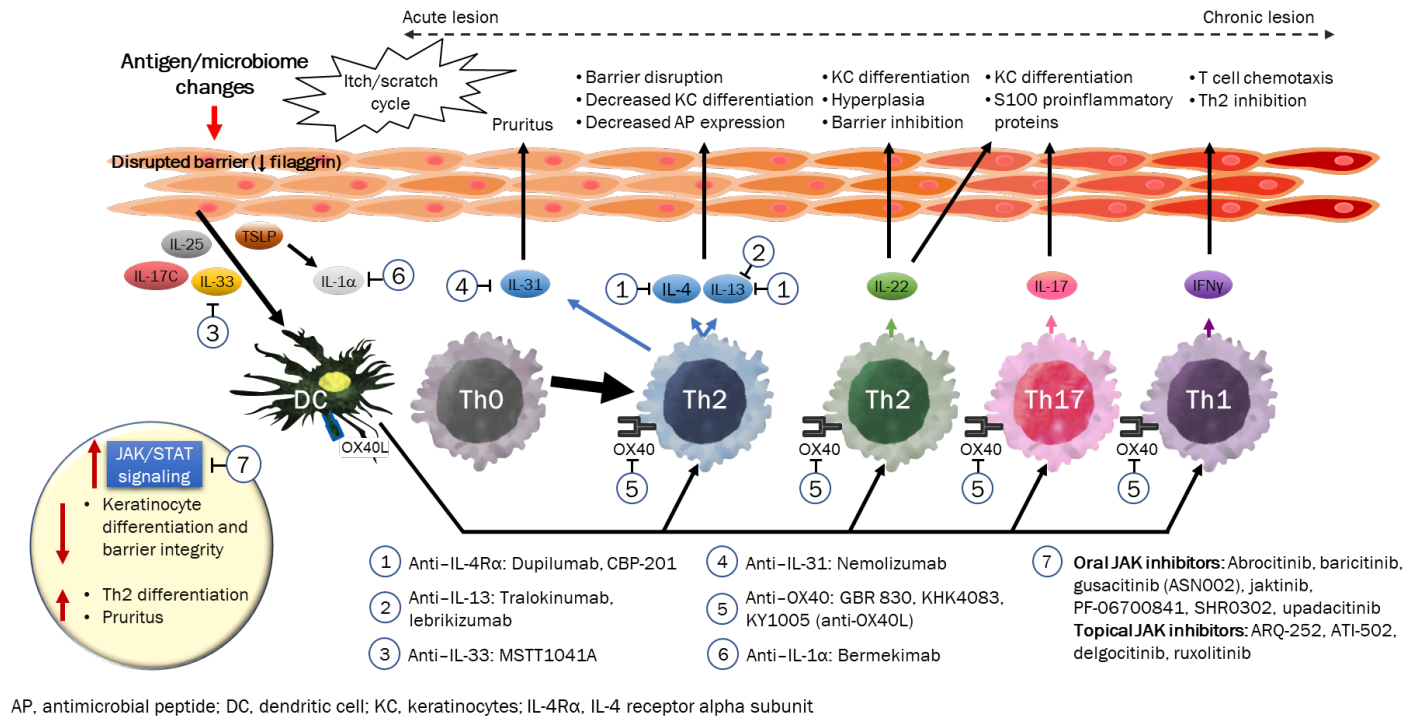
The emerging immunopathology of atopic dermatitis: Therapeutic targets



AP, antimicrobial peptide; DC, dendritic cell; KC, keratinocytes; IL-4Rα, IL-4 receptor alpha subunit

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New and Emerging Therapies

- **New:**
  - Crisaborole: topical 2016
  - Dupilumab: systemic 2017
  - Dupilumub approved for adolescents 12-17 in 2019
  - Dupilumab approved for 6-year-olds and up in 2020

- **Emerging:**
  - Monoclonal antibodies against IL-13 and 31RA
  - Phosphodiesterase- 4 inhibitors
  - JAK inhibitors
  - Transient receptor potential (TRPV1) antagonist
  - T-cell inhibitors
  - Prostaglandin/leukotriene inhibitors

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Emerging Treatments: JAK Inhibitors

Pediatric

Adult

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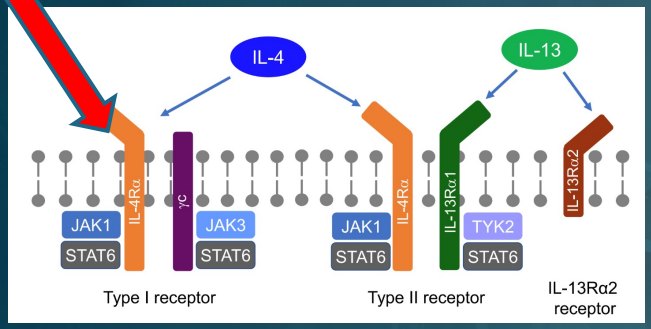
JAK-STAT Pathway

- Plays a critical role in immune system modulation
- Cytokine stimulation → intracellular JAK proteins phosphorylate STATs → STATS dimerize and translocate to the nucleus → modulate gene transcription of inflammatory mediators
- Four human JAKs:
  - JAK1
  - JAK2
  - JAK3
  - TYK2
- Inhibition of this pathway is thought to reduce T-cell activation in AD

Site of monoclonal antibody inhibition



Katoh et al. Emerging treatments for atopic dermatitis. J of Dermatol 2020

Site of JAK-STAT inhibition

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Emerging JAK Inhibitors

- Selective JAK-1 inhibitors
  - Abrocitinib
  - Upadacitinib
- JAK-1/2 inhibitors
  - Baricitinib
  - Ruxolitinib
- JAK-1/3 inhibitor
  - Tofacitinib (studied in adults)

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Abrocitinib

- 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

Gooderham et al. JAMA derm 2019.
Simpson et al. European Academy of Dermatology and Venereology 28th Congress 2019
Silverberg et al. JAMA Derm 2020.
Pfizer Announces Positive Top-Line Results from Jade TEEN Trial of Abrocitinib in Adolescents with Moderate-to-Severe Atopic Dermatitis. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-results-jade-teen-trial

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Upadacitinib

- 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)

Guttman-Yassky et al. Journal of Allergy and Clinical Immunology. 2019.
RINVOQ™ (upadacitinib) Monotherapy Shows Improvement in Skin Clearance and Itch in First Phase 3 Study for Atopic Dermatitis. Available from: https://news.abbvie.com/news/press-releases/rinvoq-upadacitinib-monotherapy-shows-improvement-in-skin-clearance-and-itch-in-first-phase-3-study-for-atopic-dermatitis.htm

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Baricitinib

- 2- or 4mg baricitinib has shown success in significantly reducing IGA and EASI scores as well as night-time awakenings, skin pain, and QOL measures in phase III trials of adult patients with AD
- Baricitinib + TCS met primary endpoint of EASI-75 in preliminary phase III data of adults with AD not otherwise controlled by cyclosporine
- **Phase III study of baricitinib in children and adolescents aged 2 to 17 years of age is currently recruiting patients (NCT03952559)**

Guttman-Yassky et al. JAAD 2019
Simpson E et al. British Journal of Dermatology. 2020
Lilly and Incyte Announce Top-Line Results from Phase 3 Study (BREEZE-AD4) Available from: https://investor.incyte.com/news-releases/news-release-details/lilly-and-incyte-announce-top-line-results-phase-3-study-breeze

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Ruxolitinib

- Topical ruxolitinib cream demonstrated superiority in terms of IGA, EASI, and NRS scores compared to triamcinolone cream in a phase II study of adults with AD
- Preliminary phase III data of ruxolitinib cream significantly reducing AD severity scores and rapid reduction in itch support the planned submission of an NDA to the FDA before the end of 2020
- **A phase I study assessing use of ruxolitinib cream in pediatric patients ages 2 to 17 years of age is currently active (NCT03257644)**

Kim BS et al. Journal of Allergy and Clinical Immunology. 2020
Kim BS et al. JAAD 2020
Incyte Announces First Presentation of Phase 3 Data from the TRuE-AD Program of Ruxolitinib Cream at the Revolutionizing Atopic Dermatitis Virtual Symposium. Available from: https://investor.incyte.com/news-releases/news-release-details/incyte-announces-first-presentation-phase-3-data-true-ad-program

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Emerging Treatments: Biologics

Pediatric

Adult

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Emerging Monoclonal Antibodies in Pediatric AD

- Monoclonal antibodies which inhibit various cytokines
  - Dupilumab: anti-IL-4, IL-13
  - Nemolizumab: anti-IL-31
  - Lebrikizumab, Tralokinumab: anti-IL-13
  - Ustekinumab: anti-IL-12, IL-23

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Dupilumab: anti IL-4, IL-13

- Shifted treatment paradigm of AD following multiple successful phase III trials in adult patients with moderate-to-severe AD
- Phase III study in 251 adolescents, patients receiving dupilumab had significant reductions in IGA and EASI compared with placebo
- Post-hoc analysis: patients receiving dupilumab q2w experienced significant improvements in AD signs, symptoms, and quality of life at 16 weeks versus placebo
- Following positive pediatric results from a phase III study, the FDA approved dupilumab as the first biologic medicine for children aged 6 to 11 years with moderate-to-severe AD
- Phase II/III safety and efficacy studies of dupilumab in patients between 6 months and 6 years of age currently in recruitment (NCT03346434)

Simpson et al. NEJM 2016
Deleuran et al. JAAD 2020
Blauvelt et al. Lancet 2017
Simpson et al. JAMA derm 2020
Paller et al. American journal of clinical dermatology. 2020

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SOLO-1 and SOLO-2: Safety profile of dupilumab through Week 28

Event	SOLO-1			SOLO-2		
	Placebo qw (n=222)	Dupilumab 300 mg q2w (n=229)	Dupilumab 300 mg qw (n=218)	Placebo qw (n=234)	Dupilumab 300 mg q2w (n=236)	Dupilumab 300 mg qw (n=237)
	Patients, n (%)					
≥1 AE	145 (65)	167 (73)	150 (69)	168 (72)	154 (65)	157 (66)
≥1 SAE	11 (5)	7 (3)	2 (1)	13 (6)	4 (2)	8 (3)
Death[a]	0	0	0	0	1 (<1)	1 (<1)
AEs leading to treatment discontinuation	2 (1)	4 (2)	4 (2)	5 (2)	2 (1)	3 (1)
Infections and infestations[b]	63 (28)	80 (35)	74 (34)	76 (33)	65 (28)	68 (29)
Skin infections (adjudicated)	18 (8)	13 (6)	14 (6)	26 (11)	14 (6)	15 (6)
Non-skin infections	49 (22)	69 (30)	67 (31)	57 (24)	58 (25)	61 (26)
Herpes viral infections[c]	9 (4)	15 (7)	9 (4)	8 (3)	10 (4)	12 (5)

Phase 3 study of dupilumab repeated the impressive efficacy seen in earlier phase trials

Herpes infections and conjunctivitis are the 2 AEs of interest, but do not appear serious; etiology of conjunctivitis unknown

- **Conjunctivitis 7-12% dupilumab; 2 % placebo**
- 26 % of patients in both studies reported a history of allergic conjunctivitis at study entry.
- Injection site reactions: 10-20% dupilumab; 7-8%placebo.

[a]Deaths were judged not to be treatment-related; 1 severe asthma attack (patient had a history of asthma since 1990), 1 suicide (patient had a history of depression and suicidal ideation, and family history of suicide); [b]MedDRA System Organ Class; [c]MedDRA High Level Term Simpson EL, et al. EADV 2016, D3T01.1C Sponsored by Sanofi and Regeneron Pharmaceuticals, Inc.

Dr. David Cohen

Nemolizumab: anti IL-31

- 30mg nemolizumab significantly improved EASI and IGA scores in phase II RCT of adults with moderate-to-severe AD; shown to induce significant reduction in pruritus
- Pharmacokinetics and safety study being conducted for children and adolescents ages 12 – 17 years with AD (NCT03921411)
- Phase III trials for adolescents and adults ages 12 and older with AD are currently in recruitment for this monoclonal antibody with putative strong anti-itch properties (NCT03989349, NCT03985943, NCT03989206)

Kabashima J Allergy Clin Immunol 2018
Silverberg et al. J Allergy Clin Immunol 2020

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Lebrikizumab: anti IL-13

- Phase II trials reporting statistically significant improvements in study primary end points (i.e. EASI, IGA, and NRS) in patients receiving treatment with lebrikizumab vs. placebo

- Ongoing trials underway assessing efficacy and safety in patients over the age of 12 with moderate-to-severe AD (NCT04146363, NCT04178967, NCT04250337, NCT04250350, NCT04392154)

Guttman-Yassky et al. *JAMA dermatology*. 2020.
Simpson et al. JAAD. 2018

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Tralokinumab: anti IL-13

- Phase IIb trial reporting that adults treated with 300 mg of tralokinumab showed significant improvements in EASI and IGA scores compared with placebo; treatment group also showed improvements in SCORAD, DLQI, and NRS vs. placebo
- Current phase III long-term extension trial for subjects with AD ages 12 years and older is currently enrolling (NCT03587805)
- Study assessing tralokinumab monotherapy for adolescent subjects ages 12 – 17 years of age with moderate-to-severe AD currently active (NCT03526861)

Wollenberg et al. *Journal of Allergy and Clinical Immunology*. 2019
Wollenberg et al. JAAD 2017

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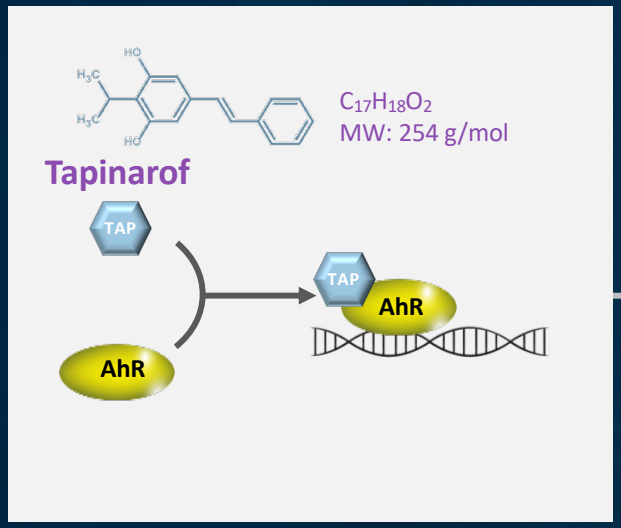
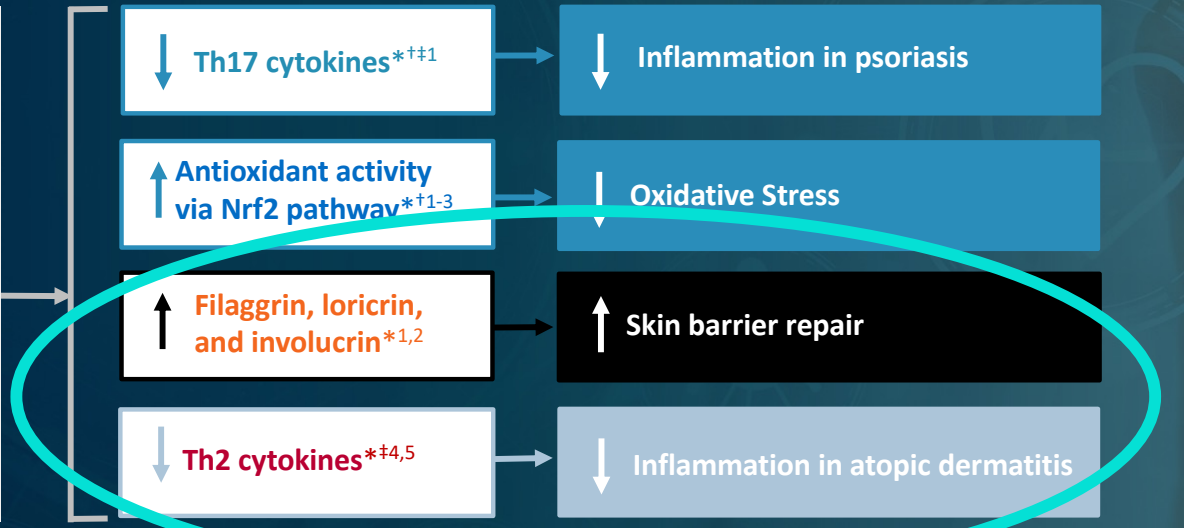
Tapinarof

- Tapinarof is a small molecule therapeutic AhR modulating agent (TAMA) that uniquely activates the AhR pathway to decrease pro-inflammatory cytokines, decrease oxidative stress, increase skin barrier proteins and re-establish skin homeostasis

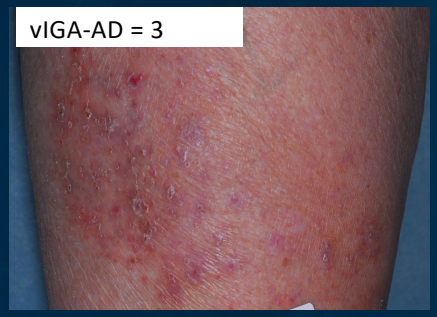
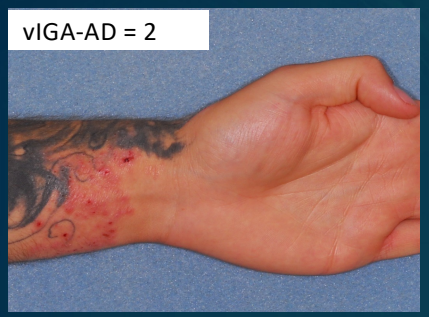
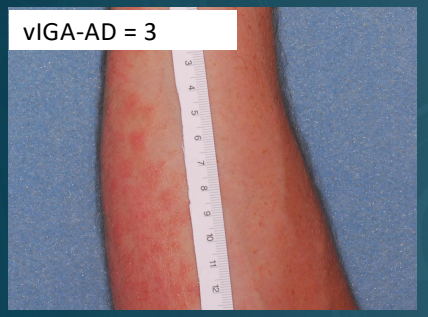
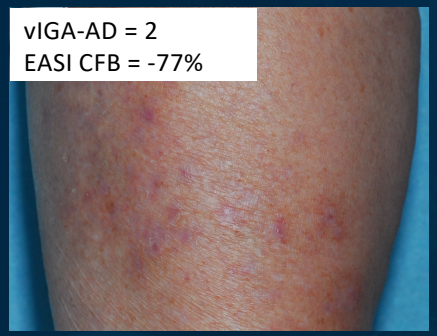
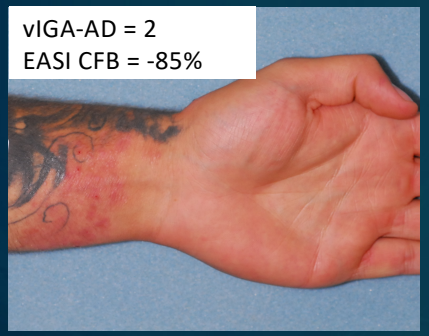
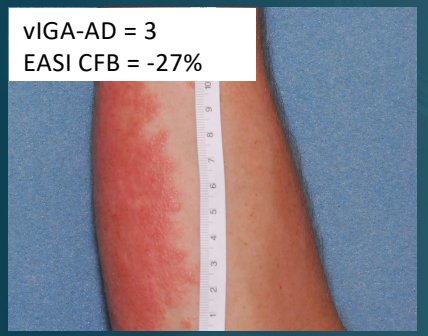




Wollenberg et al. *Journal of Allergy and Clinical Immunology*. 2019
Wollenberg et al. JAAD 2017

Dr. Leon Kircik

Roflumilast Cream Improved Severity of AD

	Roflumilast 0.15%	Roflumilast 0.05%	Vehicle
Baseline	vIGA-AD = 3 	vIGA-AD = 2 	vIGA-AD = 3 
Week 4	vIGA-AD = 2 EASI CFB = -77% 	vIGA-AD = 2 EASI CFB = -85% 	vIGA-AD = 3 EASI CFB = -27% 

- CFB: change from baseline; EASI: eczema area and severity index; vIGA-AD: validated investigator global assessment—atopic dermatitis.

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Dr. Leon Kircik

Roflumilast

The Safety and Efficacy of Roflumilast Cream 0.15% and 0.05% in Atopic Dermatitis: Phase 2 Proof-of-Concept Study

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