SIGNALS OF CHANGE IN THE MANAGEMENT OF

Atopic Dermatitis



Supported by an educational grant from Pfizer Inc.

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Jonathan I. Silverberg, MD, PhD, MPH

Associate Professor of Dermatology
Director of Clinical Research and Contact Dermatitis
George Washington University School of Medicine and Health Sciences
Washington, DC

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Zelma C. Chiesa Fuxench, MD, MSCE

Assistant Professor of Dermatology
Department of Dermatology
University of Pennsylvania
Perelman School of Medicine
Philadelphia, PA

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Melinda Gooderham, MSc, MD, FRCPC

Medical Director
SKiN Centre for Dermatology
Assistant Professor
Department of Medicine, Queen's University
Consultant Physician
Peterborough Regional Health Centre
Ontario, Canada

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Learning Objective 1



Apply clinical tools to establish disease severity to inform treatment decisions in patients with atopic dermatitis (AD).

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Learning Objective 2



Translate the results of safety and efficacy data from recent clinical trials for emerging agents to the treatment of moderate-to-severe AD.

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Learning Objective 3



Integrate patient preferences and treatment goals into shared decision-making (SDM) for moderate-to-severe AD treatment.

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Audience Response

What percentage of adult patients report adult-onset AD?

A. 1%-24%
B. 25%-50%
C. 51%-75%
D. 76%-100%
E. I don’t know

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AD: Epidemiology

- AD is one of the most common chronic inflammatory skin diseases
- AD is characterized by periods of acute disease flare
- Prevalence of AD in the United States:
  - Children ~ 20%
  - Adults ~ 3.2% to 10.7% (studies vary)
- Adult-onset AD is considered rarer
  - 1 in 4 adults report adult-onset disease
  - 30% of all cases of AD are in adult population

1. Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;70:338-351. 2. Hanifin JM, et al. *Dermatitis*. 2007;18:82-91. 3. Garmhausen D, et al. *Allergy*. 2013;68:498-506. 4. Silverberg JI, et al. *J Allergy Clin Immunol*. 2013;132:1132-1138. 5. Silverberg JI, et al. *Br J Dermatol*. 2015;173:1400-1404.

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Impact of AD on Patients



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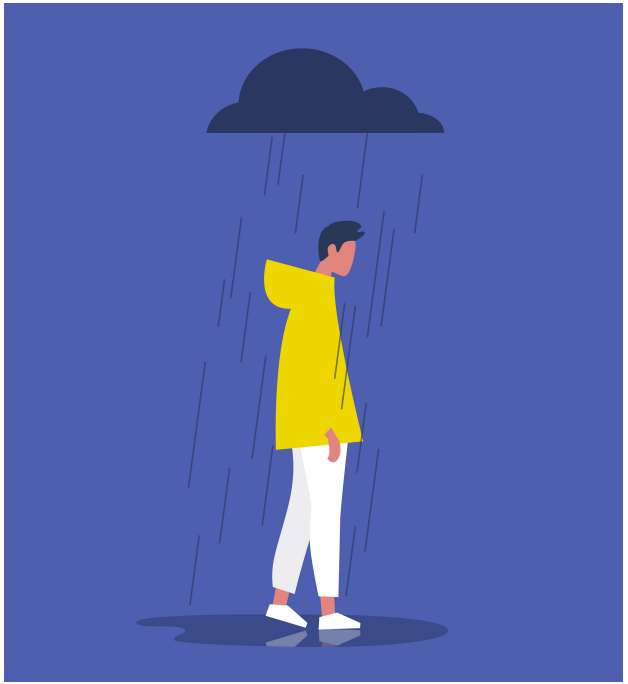
The Psychosocial Burden of AD

- Adults with AD are more likely to develop depression and anxiety[1]
  - 14% ↑ depression
  - 17% ↑ anxiety
- Review of 15 studies showed that patients with AD had:
  - 44% ↑ suicidal ideation
  - 36% ↑ suicide attempts[2]



1. Schonmann Y, et al. *J Allergy Clin Immunol Pract*. 2020;8(1):248-257.e16. 2. Armstrong A, et al. *JAMA Dermatol*. 2019;155(2):178-187.

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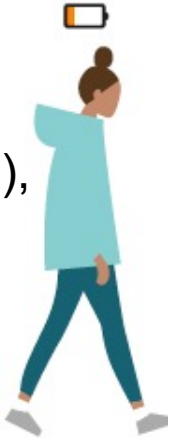
AD: Impact on Quality of Life (QoL)

Social stress, avoidance (39.1%), reduced performance at school





Lifestyle modifications: 82%
Decreased confidence: 55%

Sleep disruption: 49% of adults



Hindered career progression and performance at work: 14% of adults



1. PR Newswire Website. 2016. https://www.prnewswire.com/news-releases/new-survey-reveals-the-widespread-and-serious-impact-of-moderate-to-severe-atopic-dermatitis-on-people-living-with-the-disease-300339444.html. 2. Zuberbier T, et al. *J Allergy Clin Immunol*. 2006;118:226-232. 3. Institute for Clinical and Economic Review, 2017 Final Evidence Report – Atopic Dermatitis.

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AD Patient Burden and QoL

Cross-sectional study of adults with AD (n = 602)

- Reported Worsening
  - Overall health
  - Dissatisfied with life
  - Mental/physical health
- Severe PO-SCORAD, POEM, or PO-SCORAD-itch = very low mental health, high DLQI scores
- Limited lifestyle
- Impacted activities
- Most burdensome symptoms
  - Itch
  - Excessive dryness/scaling
  - Red/inflamed

DLQI = dermatology life quality index; PO-SCORAD = patient-oriented scoring AD; POEM = patient-oriented eczema measure

Silverberg JI, et al. *Ann Allergy Asthma Immunol.* 2018;121(3):340-347.

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Learning Objective 1



Apply clinical tools to establish disease severity to inform treatment decisions in patients with atopic dermatitis (AD).

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Audience Response

Which objective clinical tools best establish severity in moderate-to-severe AD?

A. SCORAD, EASI, IGA
B. SCORAD, DLQI
C. POEM, HADS
D. POEM, PP-NRS(itch), DLQI
E. I don’t know

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Don’t Guess: Measuring Disease Severity to Inform Treatment Decisions

- Defining moderate-to-severe disease
- Importance of consistently evaluating and documenting disease severity change
- Establishing baseline moderate-to-severe AD
  - What tools can be integrated into practice?

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Assessment of Disease Severity and Clinical Outcomes in AD

- Measures of disease severity:
  - **SCORAD: SCOR**ing **A**topic **D**ermatitis Index
  - **EASI: E**czema **A**rea and **S**everity **I**ndex
  - **IGA: I**nvestigator's **G**lobal **A**ssessment
- Measures of impact on QoL:
  - ~ 22 different scales for measuring QoL/psychological outcomes in AD
  - **DLQI: D**ermatology **L**ife **Q**uality **I**ndex/Children's Dermatology Quality of Life Index
- Symptom-specific:
  - **POEM: P**atient-**O**riented **E**czema **M**easure
  - **PP-NRS (itch)**: Peak Pruritis Numerical Rating Scale
    - Includes pain and sleep on a scale of 1-10
- Mental health
  - **HADS**: **H**ospital **A**nxiety and **D**epression **S**cale
  - **PHQ-2 or PHQ-9**: **P**atient **H**ealth **Q**uestionnaire

Eichenfield LF, et al. *J Am Acad Dermatol.* 2014;70:338-351.

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Patient-Oriented Eczema Measure (POEM)[1,2]

POEM Scoring	
0-2	Clear or almost clear
3-7	Mild eczema
8-16	Moderate eczema
17-24	Severe eczema
25-28	Very severe eczema

0	1	2	3	4
1. Over the last week, on how many days has your/your child's skin been itchy because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
2. Over the last week, on how many nights has your/your child's sleep been disturbed because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
3. Over the last week, on how many days has your/your child's skin been bleeding because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
4. Over the last week, on how many days has your/your child's skin been weeping or oozing clear fluid because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
5. Over the last week, on how many days has your/your child's skin been cracked because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
6. Over the last week, on how many days has your/your/child's skin been flaking off because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day
7. Over the last week, on how many days has your/your child's skin felt dry or rough because of the eczema?				
No days	1-2 days	3-4 days	5-6 days	Every day

Protected by copyright but is freely available and can be downloaded for use: https://www.nottingham.ac.uk/research/groups/cebd/resources/poem.aspx.
1. Charman CR, et al. *Br J Dermatol*. 2013;169(6):1326-1332. 2. Charman CR, et al. *Arch Dermatol*. 2004;140:1513-1519.

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Does the patient have moderate-to-severe AD?

Defined by lesional severity and extent and/or significant impact on QoL (including social, emotional, and school/professional functioning)

Has adequate patient education been provided, including the following?

- Avoid triggers
- Stress importance of adherence
- Optimize topical therapy (undertreatment and overtreatment)
- Address topical steroid phobia
- Consider structured educational intervention (eczema school)

Has intensive topical therapy been given in an adequate trial?

Appropriate amounts of medium- to high-potency topical anti-inflammatory therapy for 1-4 weeks followed by proactive therapy for maintenance; Consider wet wrap therapy and soak and seal

Have alternative diagnoses been considered?

- Have infections been managed?
- Has patch testing for contact allergy been considered?
- Is referral to allergy services required for further testing and optimization of allergic rhinitis/asthma management?

Does the patient still have persistent moderate-to-severe disease/impaired QoL despite topical therapy?

Consider phototherapy in select patient groups

Is phototherapy unsuccessful/unsuitable/unavailable?

Systemic therapy

Choice depends on childbearing capacity, comorbidities (i.e., renal dysfunction, diabetes, alcohol abuse), age, and preferences (e.g., injection vs. tablets)

Adapted from Simpson EL, et al. *J Am Acad Dermatol.* 2017;77(4):623-633.

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Validity of Using PRO Tools in Clinical Practice

- No single PRO captures all aspects of disease
- Validated AD severity assessment tools include:
  - **PO-SCORAD**: Subjective and objective criteria to assess extent and severity of AD symptoms
  - **DLQI**: Measurement of burden of skin disease in adults
  - **NRS-itch**: Numerical rating of itch intensity
  - Patient-reported Global AD severity

PRO = patient-reported outcome

Silverberg J, et al. *Br J Dermatol*. 2020;182(1):104-111.

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QI Project: Confidence in Using Assessment Tools

"We have a busy clinic, and I did not need one more measure that is now deemed to be important or improve quality. But, when I ***integrated POEM into my everyday clinical assessment, I saw overall patient outcomes improve*** *and patients regularly thank me for including their holistic care in our discussion as part of care.* ***I have realized the need to adjust treatment****. When we use data to drive decisions and measures to engage patients, we all win."*
- Dermatologist from Maryland

- At baseline, 13% of clinicians (n = 15) were using POEM with < 50% of patients
- 3 months post-project, 89% were using POEM with ≥ 80% of patients

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Measuring Can Be Part of Clinic!

"I was not familiar with these screening tools prior. I enjoy talking with patients and unraveling the mystery of their symptoms. They may come in for a simple eczema check-up, but ***it is their POEM and HADS scores that reveal so much more to their story and what should be addressed in their care plan****."*

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Learning Objective 2



Translate the results of safety and efficacy data from recent clinical trials for emerging agents to the treatment of moderate-to-severe AD.

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Goals for Treatment

- Maintain a state in which symptoms are mild with minimal impact on QoL[1]
- Decrease the rate of acute flares or disease exacerbation[1]
- Manage acute flares quickly and effectively[1]
- Meet individual patient therapeutic needs[1]
- Regardless of severity, early identification and aggressive treatment of AD are critical first steps to improving outcomes and lessen burden[2]

1. Augustin M, et al. *J Eur Acad Dermatol Venereol*. 2020;34(1):142-152 [corrigendum 2020;34(1):1118]. 2. Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018;120(1):10-22.

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Stepping Up to Moderate-to-Severe AD

Patient is symptomatic despite aggressive course of topical prescription therapy (corticosteroid, calcineurin inhibitor, crisaborole) for ≥ 3 weeks and following basic management recommendations for skin care, antiseptic treatment and avoidance of allergens and irritants, and particularly when there is severe and negative impact on daily activities, psychosocial health, and QoL*

- Refer to specialist
- For some patients consider acute treatment to help gain control:
  - Wet wrap therapy
  - Hospitalization

Phototherapy

Dupilumab

Systemic immunosuppressant therapy

- Cyclosporine†
- Methotrexate†
- Mycophenolate mofetil†
- Azathioprine†
- Corticosteroids‡

3-month therapeutic trial with reassessment at 4-8 weeks

*Before stepping up therapy, assess for nonadherence, potential comorbidities, and other factors that might negatively affect response to therapy;†Not FDA-approved; ‡FDA-approved but should be used only in acute flares or as rescue therapy

Boguniewicz M, et al. *Ann Allergy Asthma Immunol*. 2018;120(1):10-22.

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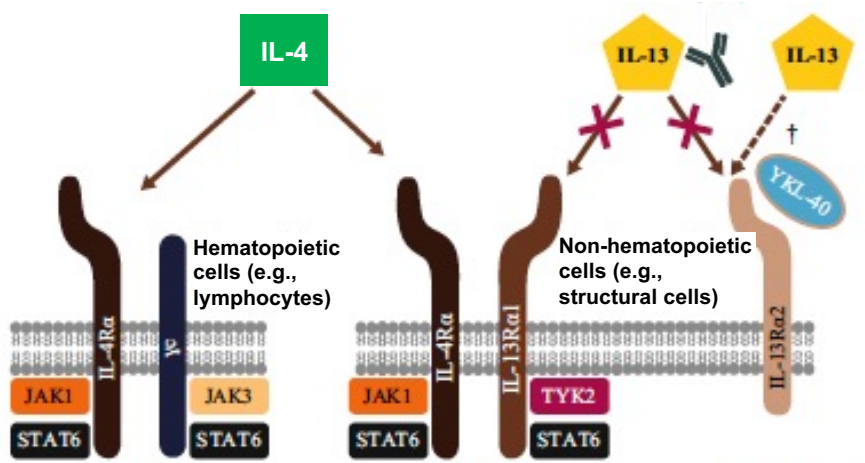
Treatment Targets in AD

Monoclonal Antibodies[1]



Type I receptor

Normal IL-4 signaling

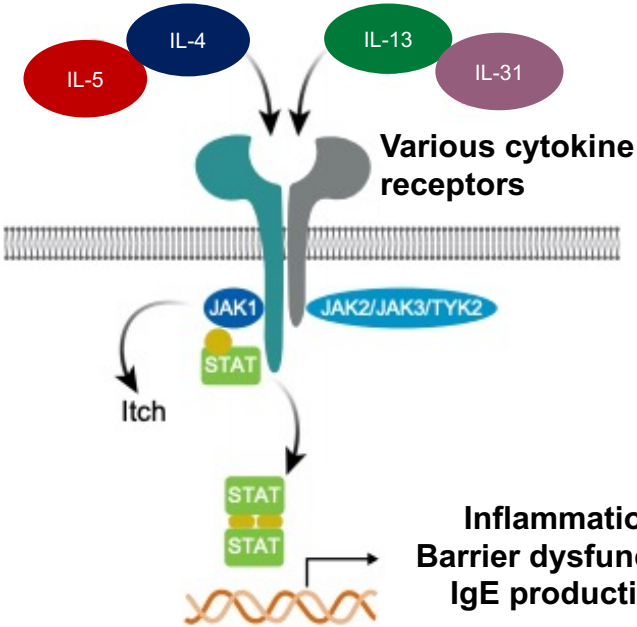
Type II receptor

Normal IL-4 signaling
No IL-13 signaling

IL-13Rα2 receptor

Signaling or decoy?

JAK Inhibitors[2]



Inflammation
Barrier dysfunction
IgE production

JAK = Janus kinase

1. Beiber T. *Allergy*. 2020;75(1):54-62. 2. Kim BS, et al. *J Allergy Clin Immunol*. 2020;145(2):572-582.

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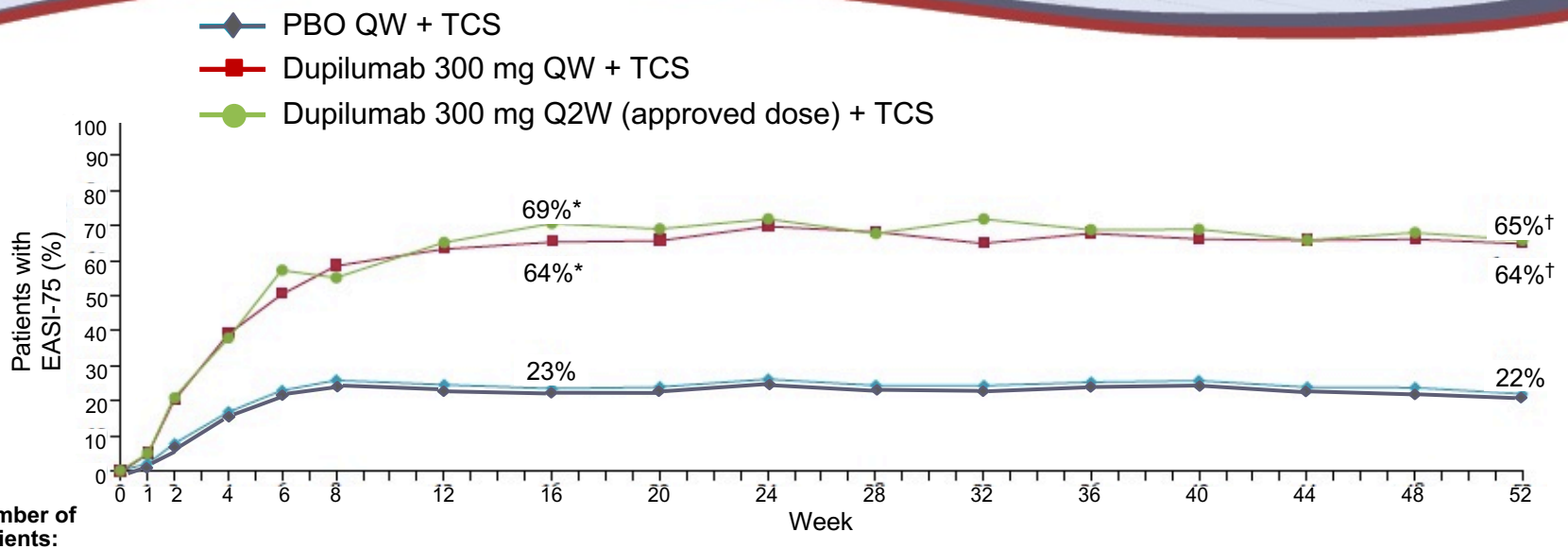
Dupilumab + TCS: Impact on EASI-75



Number of Patients:																
Dupilumab QW (n = 270)	15	56	106	136	158	171	176	177	188	184	174	182	177	176	177	173
Dupilumab Q2W (n = 89)	5	19	34	51	49	58	63	61	64	60	64	61	61	58	60	58
PBO (n = 264)	6	22	45	61	68	65	62	63	69	64	64	66	67	62	62	57

FAS = full analysis set; qw = every week; PBO = placebo; q2w = every 2 weeks; TCS = topical corticosteroid
*$p < .0001$ vs. PBO + TCS (FAS); †$p < .0001$ vs. PBO + TCS (FAS-52)
Blauvelt A, et al. *Lancet*. 2017;389:2287-2303.

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Dupilumab: Safety and Efficacy

- Favorable safety, sustained efficacy for up to 3 years in open-label study of adults with moderate-to-severe AD[1]
- AD signs and symptoms showed sustained improvements during treatment
  - EASI-75: 1.4 (3.2, - 95.4%) and weekly
  - NRS-Itch: 2.2 (1.8, - 65.4%) at week 148[2]
- Common adverse events (AEs) in ≥ 5% of patients: nasopharyngitis, conjunctivitis, headache, oral herpes, injection-site reactions[2]

1. Deleuran M, et al. *J Am Acad Dermatol*. 2020;82(2):377-388. 2. Beck LA, et al. *Am J Clin Dermatol*. 2020;21(4):567-577.

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Questions



Recorded on March 1, 2021

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Emerging Therapies



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Agents in Phase III for AD‡

Drug	Main Target	Delivery Vehicle
Abrocitinib	JAK1	Oral
Upadacitinib	JAK1	Oral
Baricitinib	JAK1/JAK2	Oral
Tralokinumab	IL-13 inhibitor	Subcutaneous injection

IL = interleukin
‡Not currently FDA-approved for AD
Nezamololama N, et al. *Drugs Context.* 2020;9:2020-8-5.

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Audience Response

In the JADE-COMPARE trial, at what dosage does abrocitinib have a better itch response than dupilumab or placebo?

A. 300 mg
B. 200 mg
C. 100 mg
D. 50 mg
E. I’m not sure

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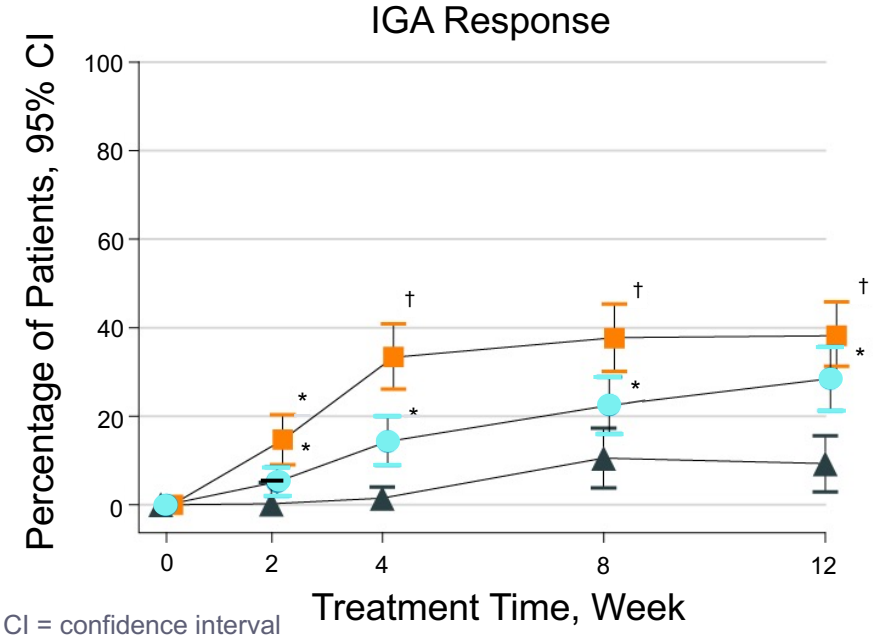
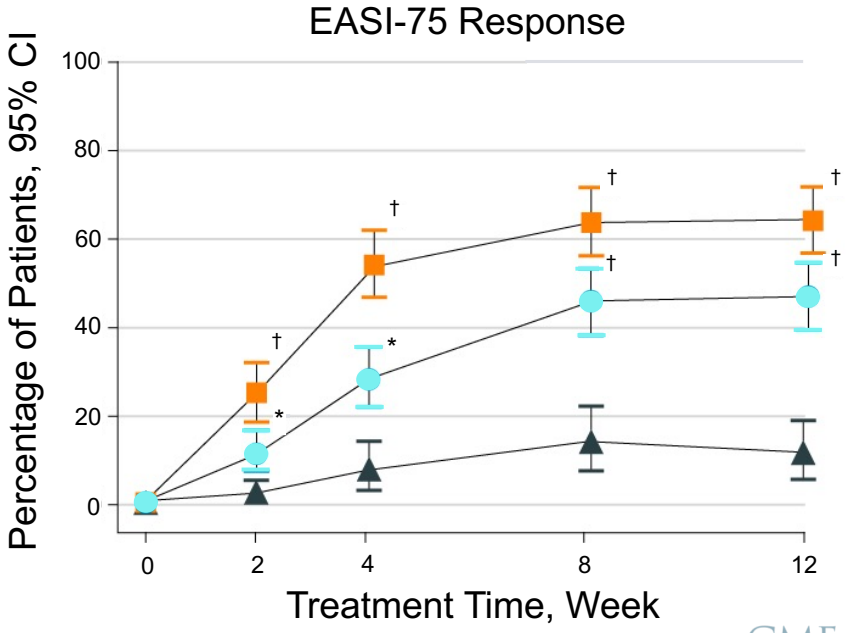
Abrocitinib‡: JADE-MONO-2

▲ PBO (n = 77)
● Abrocitinib 100 mg (n = 155)
■ Abrocitinib 200 mg (n = 155 IGA; n = 154 EASI-75)





CI = confidence interval
*$p < .05$; †$p < .001$; ‡Not currently FDA-approved for AD
Silverberg JI, et al. *JAMA Dermatol*. 2020;156(8):863-873.

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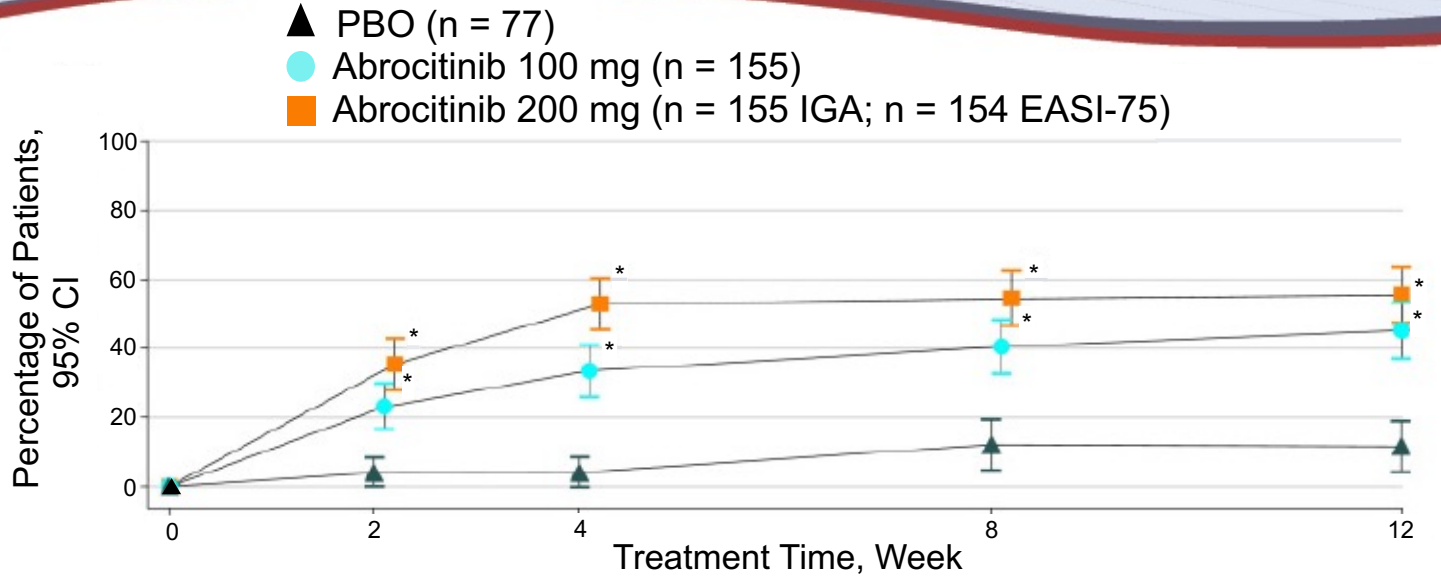
Abrocitinib‡: JADE-MONO-2
PP-NRS Response



- PP-NRS response defined as improvement of at least 4 points from baseline
- Reduced severity of pruritus compared to placebo within 24 hours after treatment initiation and through week 12

*$p \leq .001$ vs. PBO; ‡ Not currently FDA-approved for AD

Silverberg JI, et al. *JAMA Dermatol*. 2020;156(8):863-873.

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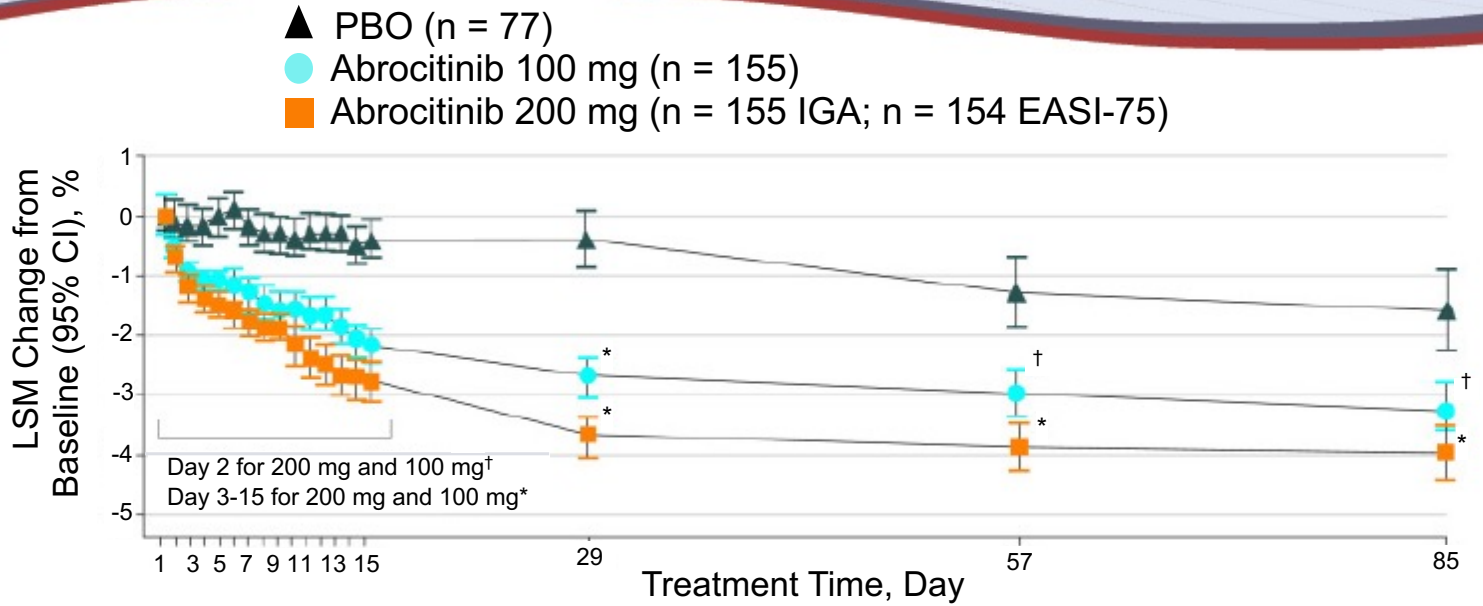
Abrocitinib‡: JADE-MONO-2
Change in PP-NRS from Baseline



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*$p \leq .001$ vs. PBO; †$p < .05$ vs. PBO; ‡Not currently FDA-approved for AD

Silverberg JI, et al. *JAMA Dermatol*. 2020;156(8):863-873.

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Abrocitinib‡: JADE-MONO-2

	Treatment Group, n (%)		
	Placebo n = 78	Abrocitinib 100 mg n = 158	Abrocitinib 200 mg n = 155
Deaths	0	1 (0.6%)	0
SAE of any cause	1 (1.3%)	5 (3.2%)	2 (1.3%)
Most frequently reported TEAEs (≥ 3% in any treatment group)			
Nausea	2 (2.6%)	12 (7.6%)	22 (14.2%)
Nasopharyngitis	5 (6.4%)	20 (12.7%)	12 (7.7%)
Headache	2 (2.6%)	9 (5.7%)	12 (7.7%)
Upper respiratory tract infection (URTI)	3 (3.8%)	14 (8.9%)	5 (3.2%)
Dermatitis atopic	12 (15.4%)	9 (5.7%)	6 (3.9%)
Acne	0	2 (1.3%)	9 (5.8%)
Vomiting	1 (1.3%)	2 (1.3%)	8 (5.2%)
Upper abdominal pain	0	2 (1.3%)	6 (3.9%)
Blood CPK increased	2 (2.6%)	3 (1.9%)	5 (3.2%)
Folliculitis	2 (2.6%)	0	5 (3.2%)
Thrombocytopenia	0	0	5 (3.2%)

‡Not currently FDA-approved for AD
CPK = creatine phosphokinase; SAE = serious AE; TEAE = treatment-emergent AE
Silverberg JI, et al. *JAMA Dermatol*. 2020;156(8):863-873.

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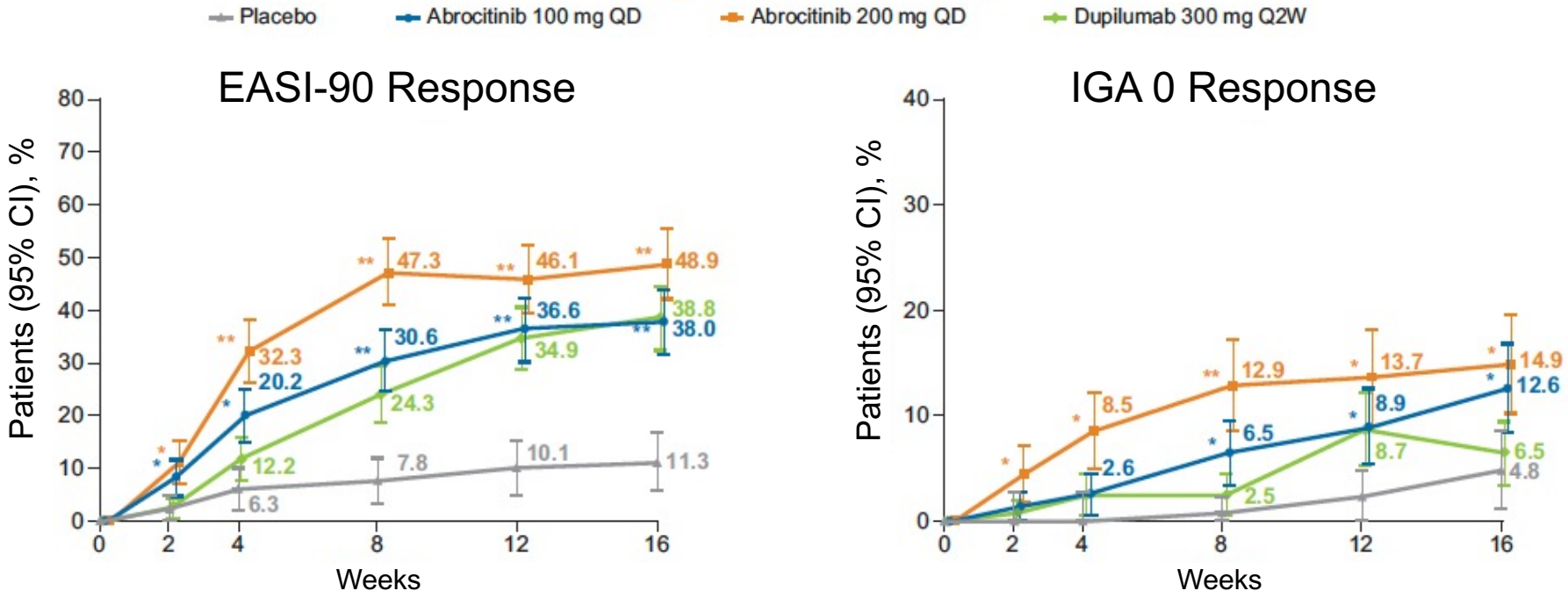
Abrocitinib‡: JADE COMPARE

Proportion of Patients Achieving EASI-90 and IGA 0 Response



*$p < .05$; **$p < .0001$ vs. placebo; ‡Not currently FDA-approved for AD

Bieber T, Simpson EL, Silverberg JI, et al. *N Engl J Med.* 2021;384:1101-1112.

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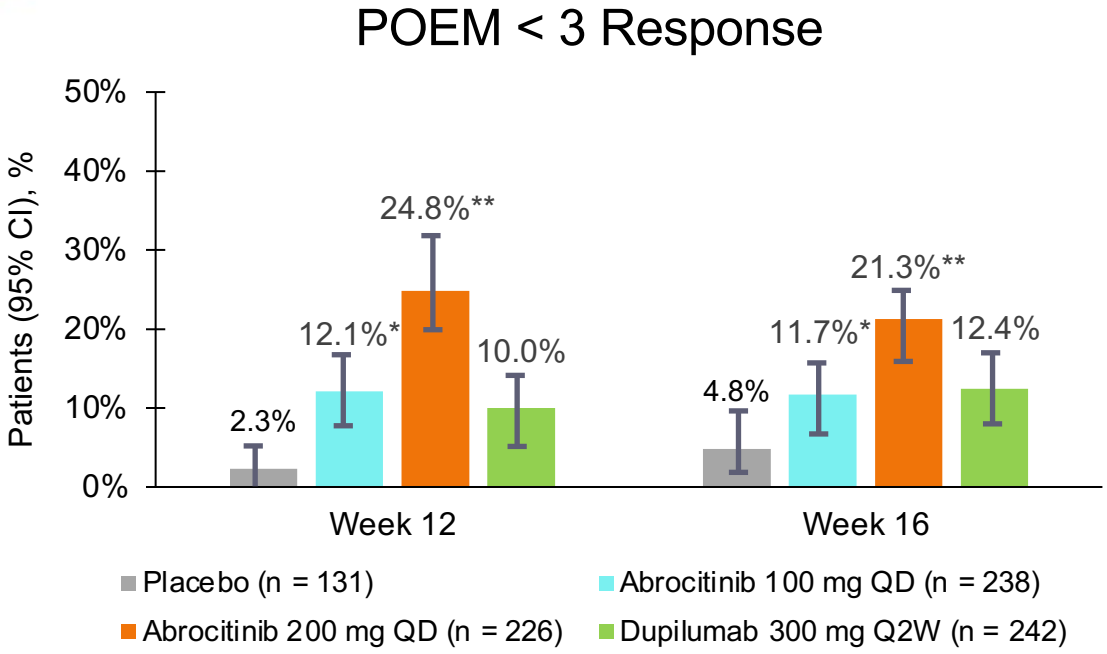
Abrocitinib‡: JADE COMPARE
POEM < 3 Response



- A greater proportion of patients met the criteria for POEM < 3 response at weeks 12 and 16 with abrocitinib 200 mg & abrocitinib 100 mg compared to placebo

*$p < 0.05$; **$p < 0.0001$ vs placebo
‡Not currently FDA-approved for AD
Bieber T, Simpson EL, Silverberg JI, et al. *N Engl J Med.* 2021;384:1101-1112.

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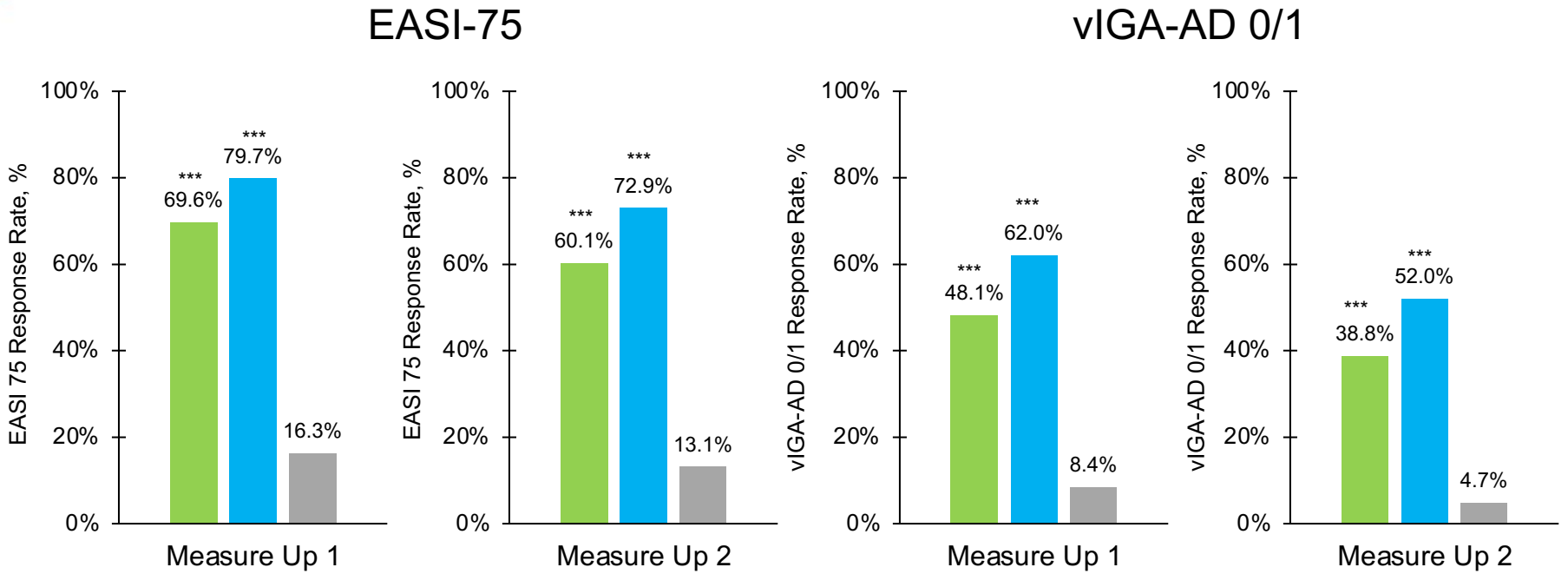
Upadacitinib‡: Measure Up 1 and 2



UPA = upadacitinib
‡Not currently FDA-approved for AD
***$p \leq .001$ vs. placebo (multiplicity controlled)

Guttman-Yassky E, et al. Presented at: European Academy of Dermatology and Venereology Congress; 2020. Abstract D3T03.4B.

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Upadacitinib‡

Measure Up 1 and 2 Phase III Studies (16 Weeks)

	Measure Up 1			Measure Up 2		
	Patients, n (%)					
	UPA 15 mg n = 281	UPA 30 mg n = 285	PBO n = 281	UPA 15 mg n = 276	UPA 30 mg n = 282	PBO n = 278
Any TEAE	176 (62.6)	209 (73.3)	166 (59.1)	166 (60.1)	173 (61.3)	146 (52.5)
SAE	6 (2.1)	8 (2.8)	8 (2.8)	5 (1.8)	7 (2.5)	8 (2.9)
AEs leading to discontinuation	4 (1.4)	11 (3.9)	12 (4.3)	11 (4.0)	7 (2.5)	12 (4.3)
Most frequently reported TEAEs (≥ 5% in any treatment group)						
Acne	19 (6.8)	49 (17.2)	6 (2.1)	35 (12.7)	41 (14.5)	6 (2.2)
Upper RTI	25 (8.9)	38 (13.3)	20 (7.1)	19 (6.9)	17 (6.0)	12 (4.3)
Nasopharyngitis	22 (7.8)	33 (11.6)	16 (5.7)	16 (5.8)	18 (6.4)	13 (4.7)
Headache	14 (5.0)	19 (6.7)	12 (4.3)	18 (6.5)	20 (7.1)	11 (4.0)
Blood CPK increased	16 (5.7)	16 (5.6)	7 (2.5)	9 (3.3)	12 (4.3)	5 (1.8)
Dermatitis atopic	9 (3.2)	4 (1.4)	28 (9.3)	8 (2.9)	4 (1.4)	28 (9.4)

‡Not currently FDA-approved for AD

Guttman-Yassky E, et al. Presented at: European Academy of Dermatology and Venereology Congress; 2020. Abstract D3T03.4B.

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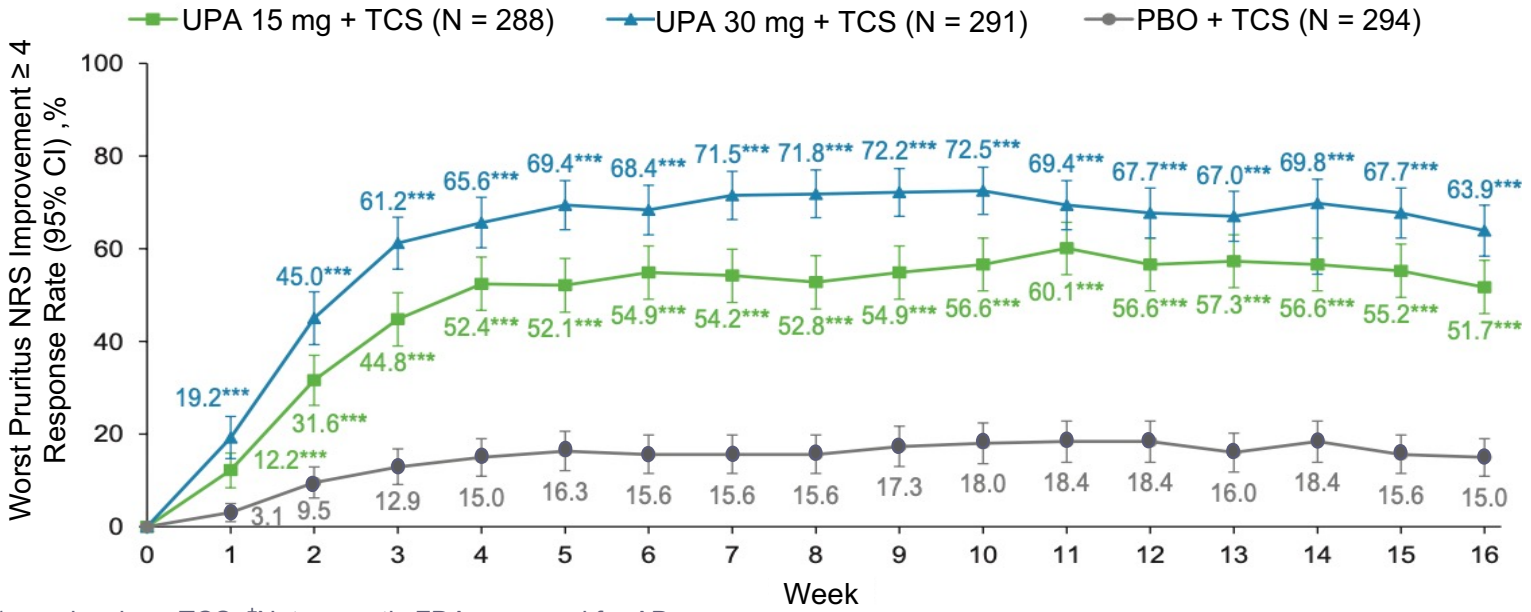
Upadacitinib‡: AD UP

NRS Improvement ≥ 4

- Phase IIb study: once daily UPA 15 mg or 30 mg monotherapy improved AD
- Portion of patients able to discontinue TCS while maintaining strong treatment response



***$p < .001$ vs. placebo + TCS; ‡Not currently FDA-approved for AD

Reich K, et al. Presented at the 3rd Revolutionizing Atopic Dermatitis Virtual Conference, December 13-14, 2020.

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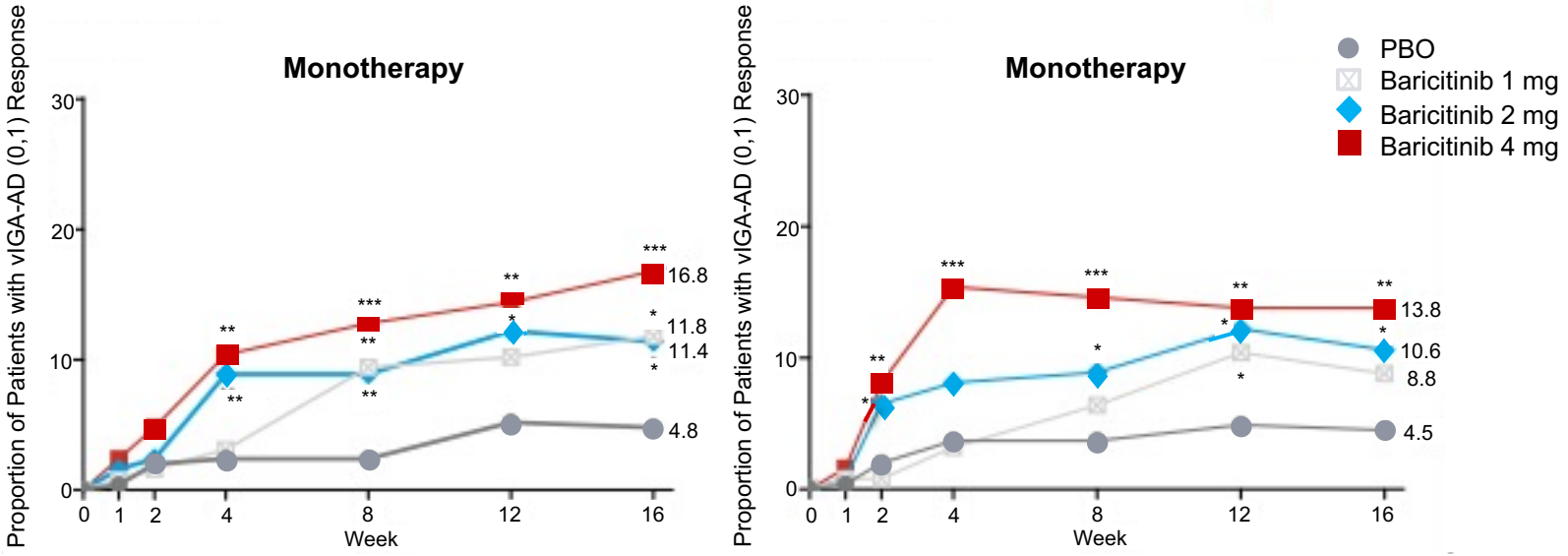
Baricitinib‡: BREEZE-AD1 and -AD2

Proportion of Patients Achieving vIGA-AD (0,1) Response



- At week 16, more patients achieved the primary endpoint of v-IGA on baricitinib 4 mg and 2 mg vs. PBO
- Improvement in itch was achieved as early as week 1 for 4 mg, week 2 for 2 mg
- Improvements in night awakening, skin pain, and QoL measures were observed by week 1 for 4 mg, week 2 for 2 mg

*$p \leq .05$; **$p \leq .01$; ***$p \leq .001$ vs. placebo; ‡Not currently FDA-approved for AD

Simpson EL, et al. *Br J Dermatol*. 2020;183(2):242-255.

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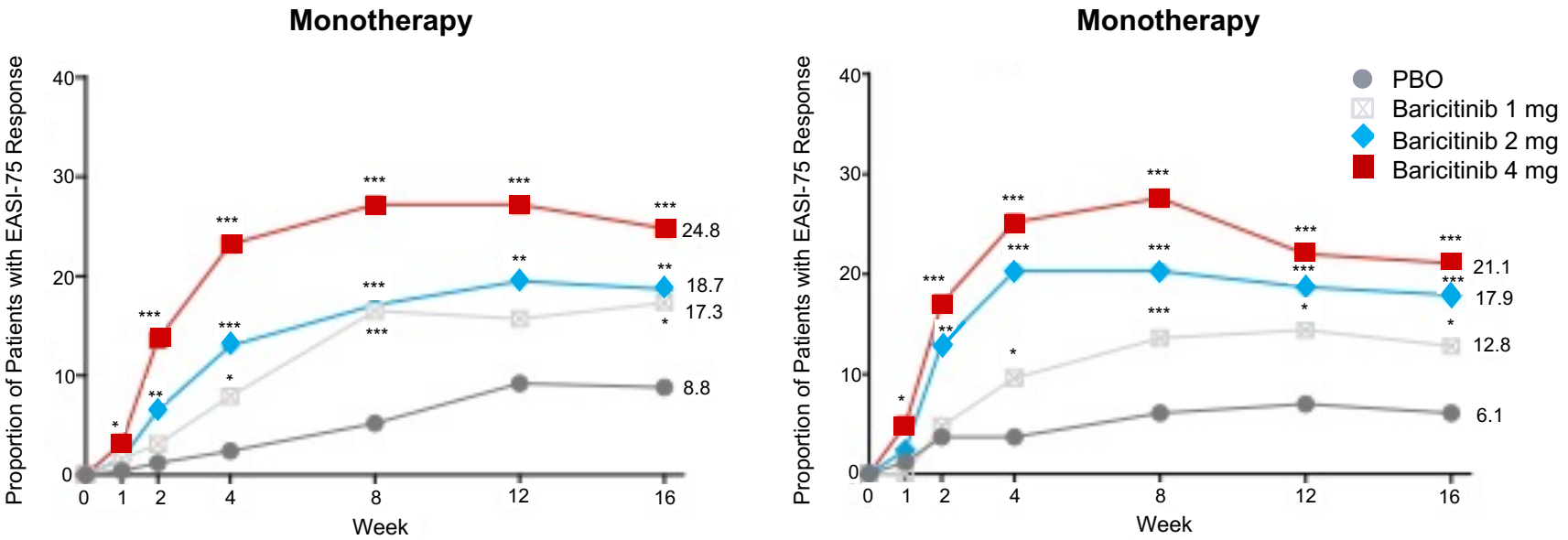
Baricitinib‡: BREEZE-AD1 and -AD2

Proportion of Patients Achieving EASI-75



‡Not currently FDA-approved for AD

*$p \leq .05$; **$p \leq .01$; ***$p \leq .001$ vs. placebo for analysis of comparing baricitinib with PBO

Simpson EL, et al. *Br J Dermatol*. 2020;183(2):242-255.

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Baricitinib‡
BREEZE-AD 1/2 Phase III Studies (16 Weeks)

	BREEZE-AD 1				BREEZE-AD 2			
	Patients , n (%)							
	Placebo (n = 249)	BARI 1 mg (n = 127)	BARI 2 mg (n = 123)	BARI 4 mg (n = 125)	Placebo (n = 244)	BARI 1 mg (n = 124)	BARI 2 mg (n = 123)	BARI 4 mg (n = 123)
Any TEAE	**135 (54.2)**	**69 (54.3)**	**71 (57.7)**	**73 (58.4)**	**137 (56.1)**	**66 (53.2)**	**71 (57.7)**	**66 (53.7)**
Serious AEs	6 (2.4)	1 (0.8)	0	1 (1.6)	9 (3.7)	9 (7.3)	3 (2.4)	1 (0.8)
Death	0	0	0	0	0	0	0	0
AEs leading to study discontinuation	4 (1.6)	2 (1.6)	1 (0.8)	1 (0.8)	2 (0.8)	7 (5.6)	3 (2.4)	2 (1.6)
Most frequent TEAEs								
Nasopharyngitis	26 (10.4)	22 (17.3)	12 (9.8)	12 (9.6)	30 (12.3)	13 (10.5)	16 (13.0)	10 (8.1)
URTI	6 (2.4)	(0.8)	3 (2.4)	4 (3.2)	5 (2.0)	6 (4.8)	5 (4.1)	4 (3.3)
Herpes simplex[a,b]	**3 (1.2)**	**7 (5.5)**	**4 (3.3)**	**9 (7.2)**	**11 (4.5)**	**6 (4.8)**	**7 (5.7)**	**5 (4.1)**
Urinary tract infection	4 (1.6)	1 (0·8)	2 (1.6)	4 (3·2)	3 (1.2)	0	0	2 (1.6)
Skin infection requiring antibiotics	11 (4.4)	1 (1.8)	6 (4.9)	4 (3.2)	19 (7.8)	6 (4.8)	9 (7.3)	6 (4.9)
Headache	16 (6.4)	7 (5·5)	14 (11.4)	10 (8.0)	5 (2.0)	6 (4.8)	9 (7·3)	11 (8.9)
Blood CPK increased	2 (0.8)	1 (0.8)	1 (0.8)	4 (3.2)	(0.4)	4 (3.2)	1 (0.8)	7 (5.7)
Diarrhea	7 (2.8)	9 (7.1)	0	4 (3.2)	4 (1.6)	2 (1.6)	3 (2.4)	3 (2.4)
Upper abdominal pain	1 (0.4)	1 (0.8)	2 (1.6)	3 (2.4)	7 (2.9)	3 (2.4)	4 (3.3)	4 (3.3)
Conjunctivitis/keratitis	4 (1.6)	1 (0.8)	2 (1.6)	1 (0.8)	2 (0.8)	6 (4.8)	2 (1.6)	0

[a]Herpes simplex includes all herpes simplex-related terms; [b]Herpes zoster cases are not yet unblinded to investigators and groups cannot be reported: one case occurred in BREEZE-AD-1 and two cases occurred in BREEZE AD-2; ‡Not currently FDA-approved for AD

Simpson EL, et al. *Br J Dermatol*. 2020;183:242-255.

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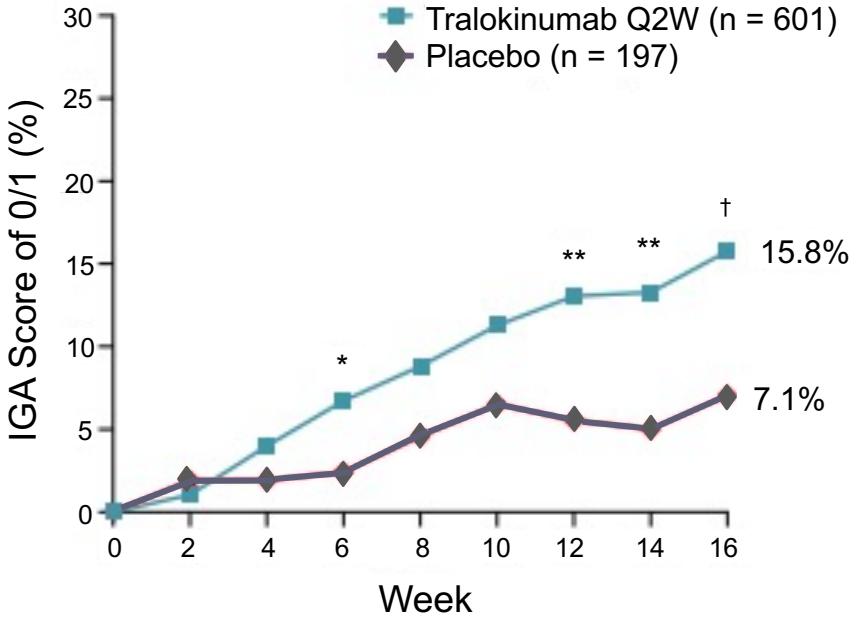
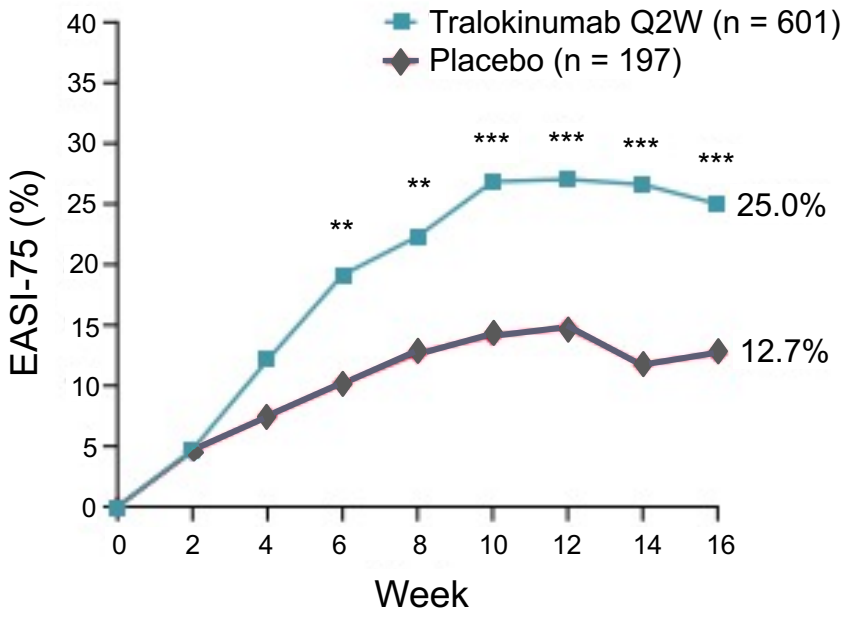
Tralokinumab‡: ECZTRA 1

Patients Achieving IGA and EASI-75





Q2W = every 2 weeks

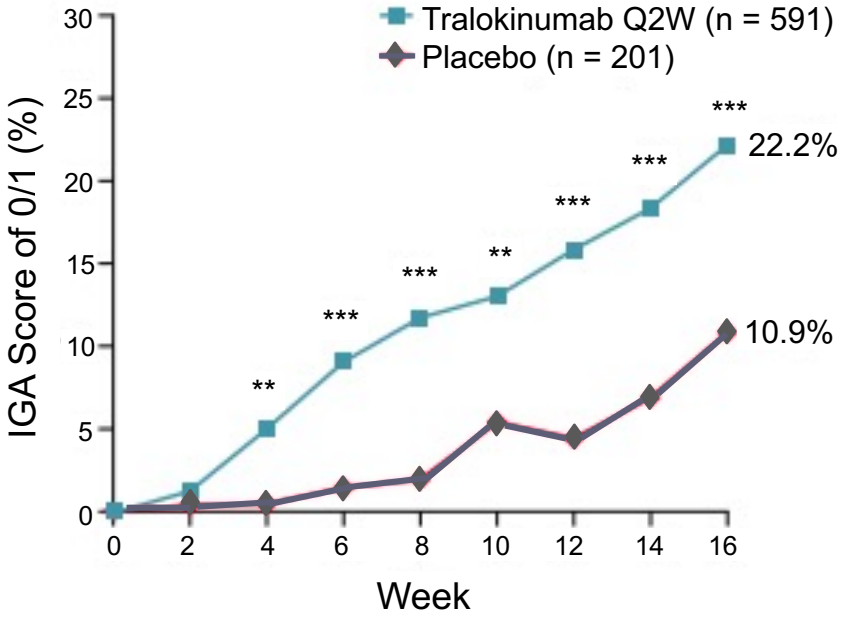
*p < .05; **p < .01; ***p < .001; †p = .002 vs. placebo; ‡Not currently FDA-approved for AD

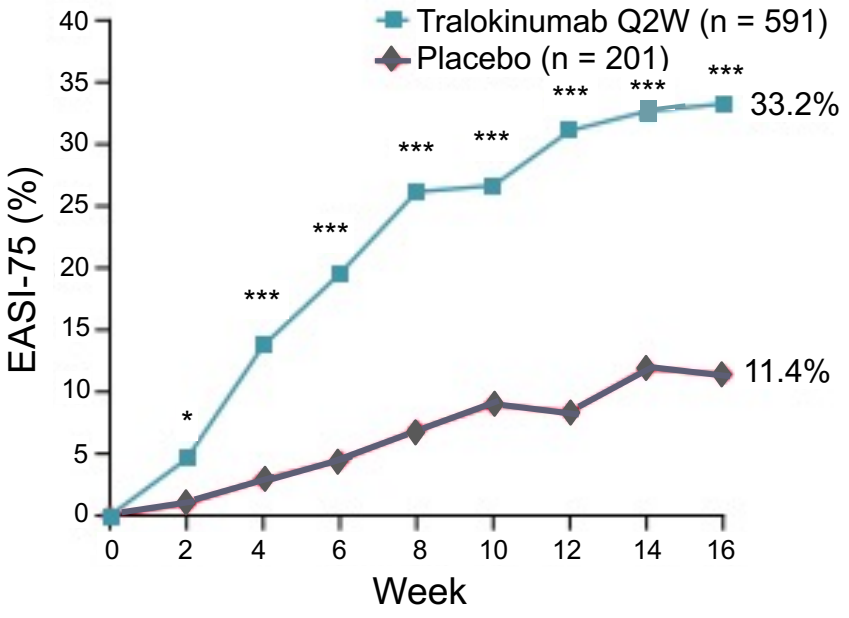
Wollenberg A, et al. *Br J Dermatol*. 2020 Sep 30. [Epub ahead of print.]

CME Outfitters

Tralokinumab‡: ECZTRA 2

Patients Achieving IGA and EASI-75





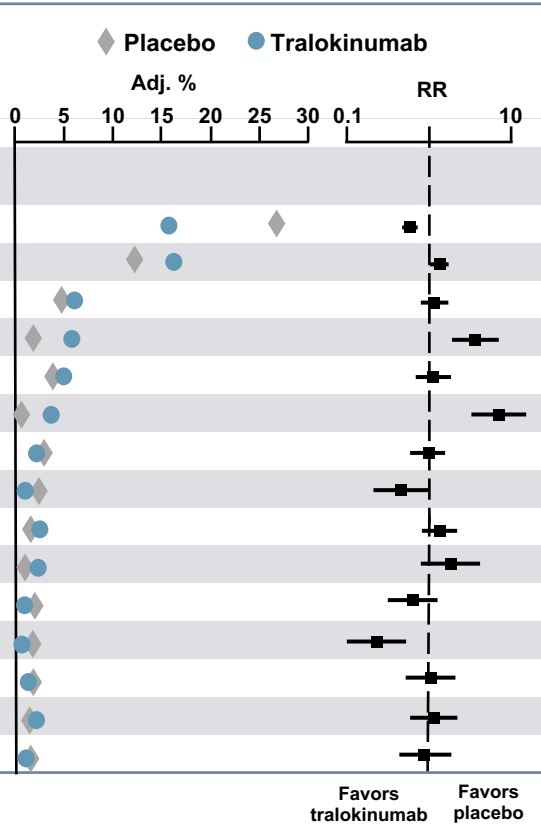
*$p < .05$; **$p < .01$; ***$p < .001$ vs. placebo; ‡Not currently FDA-approved for AD

Wollenberg A, et al. *Br J Dermatol*. 2020 Sep 30. PMID: 33000465. [Epub ahead of print.]

CME Outfitters

Tralokinumab‡
Pooled Safety Analysis of Five Phase II and III Trials

	Tralokinumab		Placebo		RR (95% CI)	*P* Value	Events (Tralokinumab)	Events (Placebo)
Most Frequent AEs*	**Adj. %**	**Adj. R**	**Adj. %**	**Adj. R**			N = 1,605	N = 680
Dermatitis atopic	15.4	68.0	26.2	139.7	0.6 (0.5, 0.7)	< .0001	356	256
Viral URTI	15.7	65.1	12.2	53.5	1.3 (1.0, 1.6)	.0362	309	99
URTI	5.6	20.8	4.8	18.5	1.1 (0.8, 1.7)	.5189	100	36
Conjunctivitis	5.4	21.0	1.9	6.9	3.3 (1.8, 5.8)	< .0001	104	13
Headache	4.6	21.6	3.9	19.6	1.1 (0.8, 1.6)	.5394	102	37
Injection site reaction	3.5	22.9	0.3	4.0	6.4 (3.0, 13.8)	< .0001	110	7
Pruritus	2.6	10.6	3.0	13.1	1.0 (0.6, 1.6)	.8977	57	24
Skin infection	1.1	4.0	2.5	9.0	0.5 (0.3, 1.0)	.0599	21	16
Injection site pain	2.3	13.4	1.7	11.8	1.3 (0.8, 2.2)	.2392	69	21
Conjunctivitis allergic	2.0	7.1	1.1	4.3	1.8 (0.9, 4.0)	.1199	36	8
Nausea	1.0	4.2	1.9	7.3	0.6 (0.3, 1.3)	.1938	22	14
Dermatitis infected	0.5	1.6	1.8	8.8	0.2 (0.1, 0.5)	.0002	9	17
Asthma	1.5	6.5	1.8	6.4	1.1 (0.6, 2.1)	.8027	32	12
Diarrhea	1.8	6.8	1.6	6.1	1.1 (0.6, 2.2)	.7323	33	12
Influenza	1.3	4.5	1.7	6.1	0.9 (0.4, 1.8)	.7498	24	11



Adj. = adjusted; R = rate; RR = risk ratio
*As defined by MedDRA preferred term; ‡Not currently FDA-approved for AD
Simpson E, et al. Poster presented at 29th EADV Congress, October 29-31, 2020 (virtual). P0218.

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Faculty Discussion



Provided by
CME Outfitters

Learning Objective 3



Integrate patient preferences and treatment goals into SDM for moderate-to-severe AD treatment.

Provided by CME Outfitters

Audience Response

Which of the following is not an example of SDM that engages patients in their care?

A. Show them the options for treatment and arrive at the decision together
B. Provide the patient with information about AD and their treatment options
C. Post updates on progress in the patient portal as an efficient way for the patient to stay current rather than discuss in time-limited visits
D. Encourage use of patient self-assessment tools
E. I'm not sure

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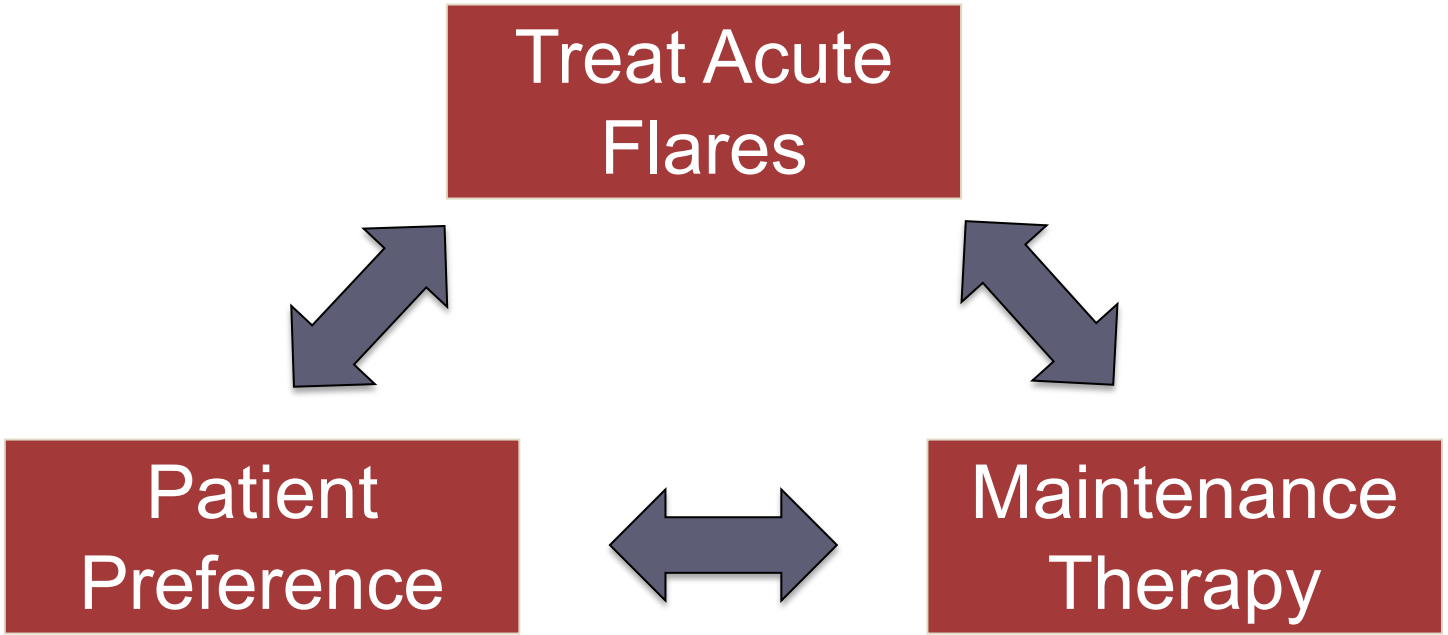
Considerations for Treatment



1. Wang D, Beck LA. *Am J Clin Dermatol.* 2016;17:425-443. 2. Saeki H, et al. *J Dermatol.* 2016;43:1117-1145.
3. Ring J, et al. *J Eur Acad Dermatol Venereol.* 2012;26:1045-1060. 4. Ring J, et al. *J Eur Acad Dermatol Venereol.* 2012;26:1176-1193.

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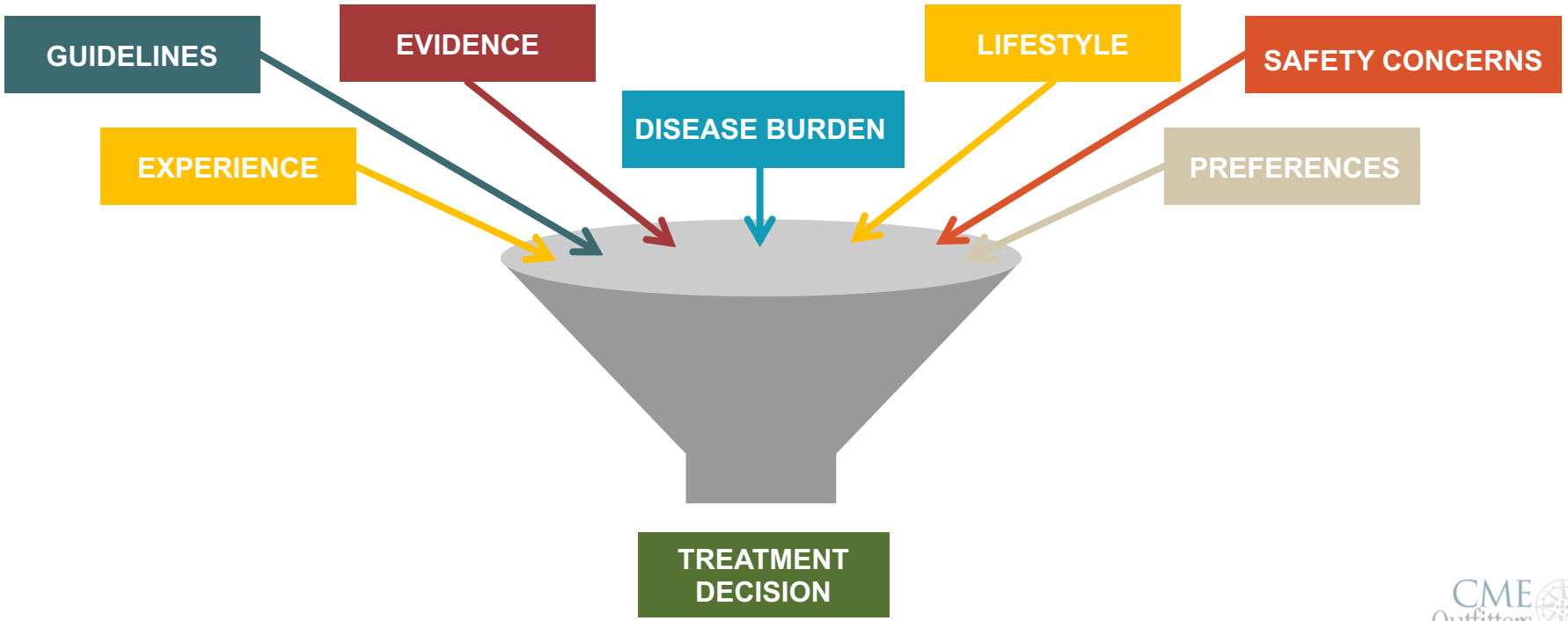
Factors Influencing Treatment Decisions



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Patient Engagement in Their Care

- Today's patients and their families want more than treatment; they want to be engaged in their care



Romero L. Healthcare IT News. 2020. https://www.healthcareitnews.com/news/telehealth-and-clinical-decision-support-ideal-synergy-patient-clinician-engagement.

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Barriers to SDM in Dermatology





- Barriers cited most frequently are time and potential to lengthen visit
  - Time investment may be recouped in shorter follow-up visits
- Low patient health literacy may prevent full engagement by patient
- Many patients do not expect to be involved in SDM and may be unaware of the evidence base of their options

Morrison T, et al. *JAMA Dermatol*. 2021;157(3):330-337.

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Patient Satisfaction

- Treatment satisfaction defined as degree patients perceive treatment fulfills health needs
- Reflection of patient's experience with therapeutic process such as duration, outcomes, and benefit
- Treatment satisfaction is influenced by preferences, beliefs, and adherence
- Dissatisfaction often results in nonadherence; may be interpreted as treatment failure

Salame N, et al. *Dermatology*. 2018;234(5-6):257-265.

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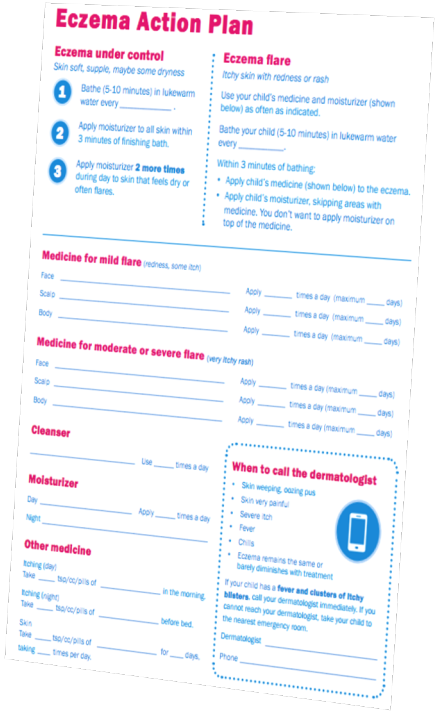
Adherence to Treatment in AD

- Strategies to improve adherence
  - Frequent follow-up appointments
  - Educational patient workshops
  - Written eczema actions plans/electronic reminders



Eczema Action Plan

Eczema under control
Skin soft, supple, maybe some dryness

1. Bathe (5-10 minutes) in lukewarm water every _____.
2. Apply moisturizer to all skin within 3 minutes of finishing bath.
3. Apply moisturizer **2 more times** during day to skin that feels dry or often flares.

Eczema flare
Itchy skin with redness or rash

Use your child's medicine and moisturizer (shown below) as often as indicated.

Bathe your child (5-10 minutes) in lukewarm water every _____.

Within 3 minutes of bathing:
- Apply child's medicine (shown below) to the eczema.
- Apply child's moisturizer, skipping areas with medicine. You don't want to apply moisturizer on top of the medicine.

Medicine for mild flare (redness, some itch)
Face _____ Apply ____ times a day (maximum ____ days)
Scalp _____ Apply ____ times a day (maximum ____ days)
Body _____ Apply ____ times a day (maximum ____ days)

Medicine for moderate or severe flare (very itchy rash)
Face _____ Apply ____ times a day (maximum ____ days)
Scalp _____ Apply ____ times a day (maximum ____ days)
Body _____ Apply ____ times a day (maximum ____ days)

Cleanser
_____ Use ____ times a day

Moisturizer
Day _____ Apply ____ times a day
Night _____

Other medicine
Itching (day)
Take ____ tsp/cc/pills of _____ in the morning.
Itching (night)
Take ____ tsp/cc/pills of _____ before bed.
Skin
Take ____ tsp/cc/pills of _____ for ____ days.
taking ____ times per day.

When to call the dermatologist
- Skin weeping, oozing pus
- Skin very painful
- Severe itch
- Fever
- Chills
- Eczema remains the same or barely diminishes with treatment

If your child has a **fever and clusters of itchy blisters**, call your dermatologist immediately. If you cannot reach your dermatologist, take your child to the nearest emergency room.

Dermatologist _____
Phone _____

1. Bass AM, et al. *J Clin Med.* 2015;4:231-242. 2. Snyder A, et al. *Cutis.* 2015;96:397-401.
3. Ellis RM, et al. *Pediatr Dermatol.* 2011;28:242-244. 4. Smith SD, et al. *Med J Aust.* 2013;199:467-469.

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Principles of SDM

- ✓ Create supportive environment for open discussion
- ✓ Clarify timeline needed for decision, offer opportunity to revisit at subsequent visits, engage family or other as appropriate
- ✓ Identify decision options and outcomes affected by options
- ✓ Check patients' understanding of everything involved with each option and outcome, provide basic information as needed
- ✓ Obtain evidence about outcomes of different options, and translate evidence to individual patient's situation

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Principles of SDM

- ✓ Select options and outcomes most relevant to patient
- ✓ Communicate expected probabilities of different outcomes for decision options
- ✓ Engage patient in discussion of his/her values and preferences
- ✓ Offer advice as the patient requests it to inform decision
- ✓ Support the patient in selection of option

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SMART Goals

Specific, Measurable, Attainable, Relevant, Timely



Measure, measure, measure…it only takes minutes!



Signals of change are coming to the treatment of AD; know the data



Engage patients in treatment decision-making to improve satisfaction and outcomes

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Questions



Recorded on March 1, 2021

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