



Ruxolitinib Cream: Phase 3 Data in Atopic Dermatitis

APRIL 6, 2020



SPEAKERS ON TODAY'S WEBCAST

- **Hervé Hoppenot**
Chief Executive Officer, Incyte

- **Lawrence Eichenfield, M.D.**
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Chief, Pediatric and Adolescent Dermatology
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- **Jim Lee, MD, PhD**
Group Vice President, Inflammation and Autoimmunity, Incyte



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FORWARD-LOOKING STATEMENTS

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: expectations regarding the impact of COVID-19 on our business, including our commercial, supply and clinical and regulatory operations; our expectations regarding our contingency plans for our clinical trials; our expectations regarding FDA review and approval for pemigatinib, capmatinib and tafasitamab; our expectations regarding the NDA submission of ruxolitinib cream for atopic dermatitis; our expectations regarding the clinical trial of ruxolitinib for COVID-19; our expectations regarding an expanded access program for ruxolitinib for COVID-19 and the adequacy of our supply of ruxolitinib; and our expectations regarding the timelines of events for ruxolitinib for atopic dermatitis and for vitiligo, including timing of data results, commercial strategy and launch plans.

These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays, including delays as a result of the COVID-19 outbreak and the measures taken to limit the outbreak; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; our dependence on relationships with and changes in the plans and expenditures of our collaboration partners; the efficacy or safety of our and our collaboration partners' product candidates; market competition; sales, marketing, manufacturing and distribution requirements, including our ability to successfully commercialize and build commercial infrastructure for any new products that become approved; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2019. We disclaim any intent or obligation to update these forward-looking statements.



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BUSINESS UPDATE IN THE TIME OF COVID-19

PRIORITY IS TO ENSURE PATIENTS MAINTAIN ACCESS TO MEDICINES

- Commercial
 - No impact to date; Incyte to report Q1 2020 in early May
- Supply
 - No supply chain issues to date; manufacturing proceeding uninterrupted
- Clinical & Regulatory
 - Limited impact to date on key goals for the year
 - No impact to date on FDA timelines for pemigatinib, tafasitamab¹ or capmatinib²
 - No impact to date on expected NDA submission for ruxolitinib cream by end of 2020
 - Future impact may depend on disease state & severity, subjects, sites and geography
 - Priorities are to:
 - Ensure continuity of care for study subjects (eg. supplying drug directly to patients)
 - Maintain the integrity of the studies (eg. adopting and providing remote / tele-monitoring tools)
 - Plans to initiate Phase 3 and EAP trials for ruxolitinib as treatment for COVID-19 associated cytokine storm



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1. Development and U.S. commercialization of tafasitamab in collaboration with MorphoSys
2. Worldwide rights to capmatinib licensed to Novartis

TWO KEY RUXOLITINIB CREAM DEVELOPMENT PROGRAMS

Atopic dermatitis



Phase 3 primary endpoints met;
long-term extension ongoing



Vitiligo



Phase 3
recruitment ongoing



ATOPIC DERMATITIS

LAWRENCE EICHENFIELD, M.D.



Atopic Dermatitis: Impact, Therapeutic Landscape and Clinical Need

Lawrence F. Eichenfield, M.D.

Professor of Dermatology and Pediatrics

Rady Children's Hospital, San Diego

University of California, San Diego



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The “Short Story” of Atopic Dermatitis

- High prevalence
 - 10 to 20% in children; 2 to 10% in adults²
- Variable course and severity
- Significant disease burden, comorbidities^{1–3,5}
- Historically, limited treatments beyond topical steroids
- High unmet need for long-term inflammatory control



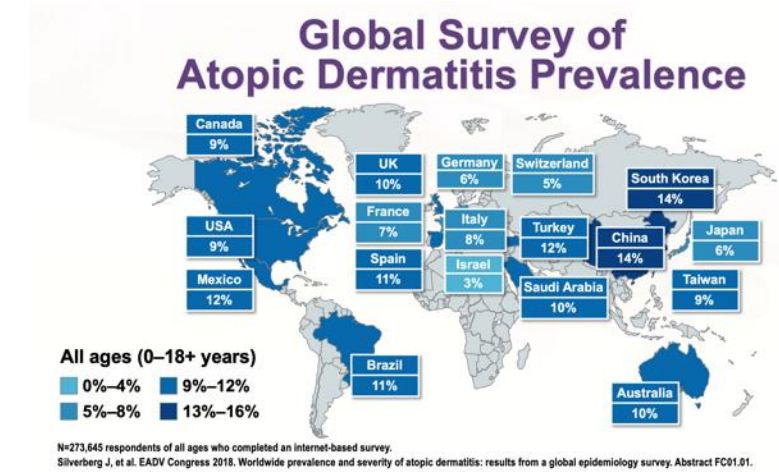
Atopic Dermatitis: What Is It?

- Atopic dermatitis (AD) is the term for the most common type of eczema
- It is an inflammatory skin disease, often starting in childhood, with a chronic, intermittent or persistent course
- It manifests as eczematous rashes, itch, bacterial colonization and secondary infections
- Disease impact is multiplied by associations with allergies (food/environmental), asthma, hayfever, neuropsychiatric effects



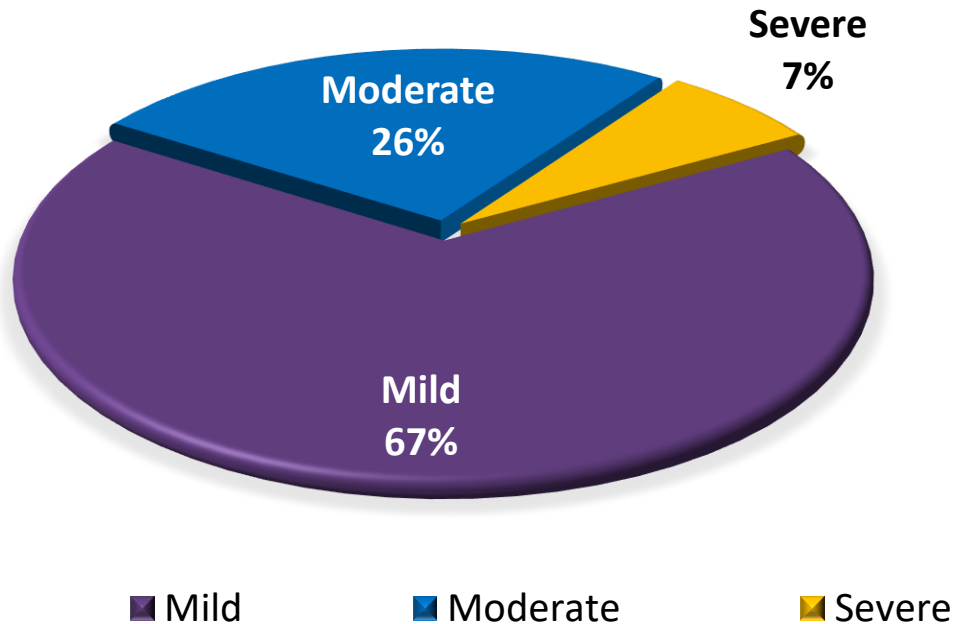
Eczema is a Worldwide Issue

- Rates in industrialized countries:
 - 8-15% of children in the first few years of life
 - Rural, non-industrialized regions: 4 to 5%
- Rates “flip” with “westernization” or emigration to industrialized areas
- In teens and adults: May persist; Or new onset disease
 - 5-7% of adults in the US estimated to have AD



Severity of Atopic Dermatitis

Classification of atopic dermatitis by severity



- *Most atopic dermatitis categorizes as mild to moderate*





Staph and Clinical Infection in AD

- Impetiginized AD
- Pustules
- Abscesses
- Rare: Cellulitis, sepsis, osteomyelitis, others
- Colonization, without infection
- Herpes infections
 - (eczema herpeticum)



Medical Consequences

- Chronic rashes
- Itch: Drives disease manifestations
- Infections (Bacterial, Viral)
- Sleep disturbance
- Atopic and non-atopic comorbidities



Atopic Dermatitis: Associated with Other Conditions!!

- Asthma
- Allergic Rhinitis and Conjunctivitis (Hayfever)
- Food Allergy
- Contact Allergy (“Occupational dermatitis”)

Tremendous “cost multipliers” in disease impact



Comorbid Allergies: Prevalence

Infants

- US population-based study of >1000 infants with AD¹
 - Approximately 11% developed asthma
 - 37% had ≥ 1 atopic comorbidities
 - Development of allergic rhinitis and food allergy correlated with baseline severity of AD

Children

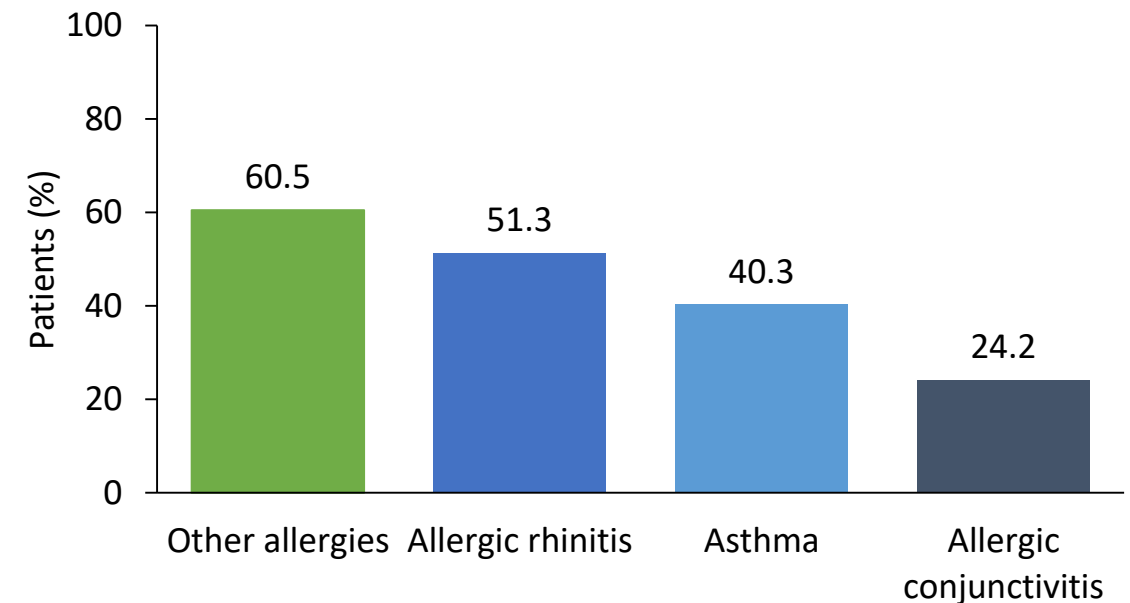
- Cross-sectional study of 2270 children with AD²
 - Nearly 80% reported another form of allergy (asthma, AR, animal allergies, food allergies, drug allergies)
 - 33% also had symptoms of asthma or AR
 - 38% also had both asthma and AR

Adults

- Retrospective cohort study of >135,000 adults with AD
 - Patients with AD have a 33% greater risk for developing other atopic diseases compared with patients without AD³

- Overall, 63–76% of adult patients with AD, regardless of severity, suffer from at least one other atopic comorbidity^{4,5}

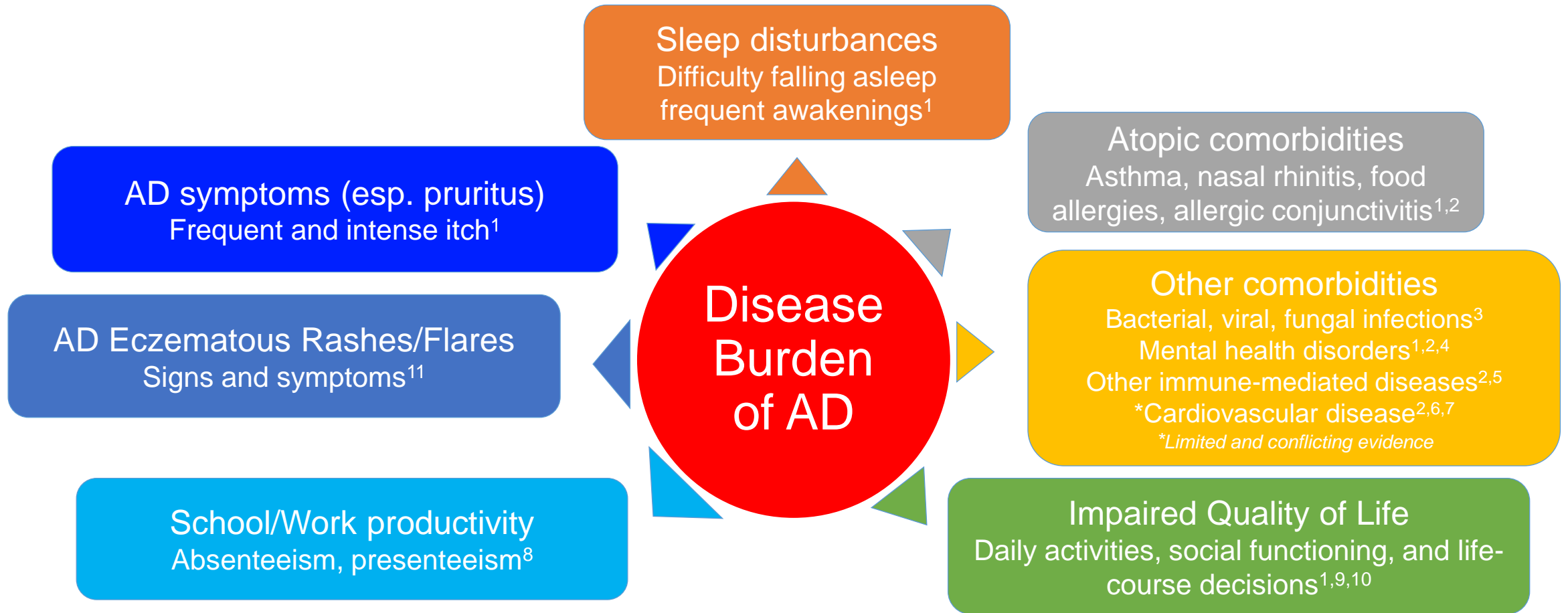
Atopic comorbidities in adults with moderate to severe AD (N=380)⁶



Comorbidities and Atopic Dermatitis

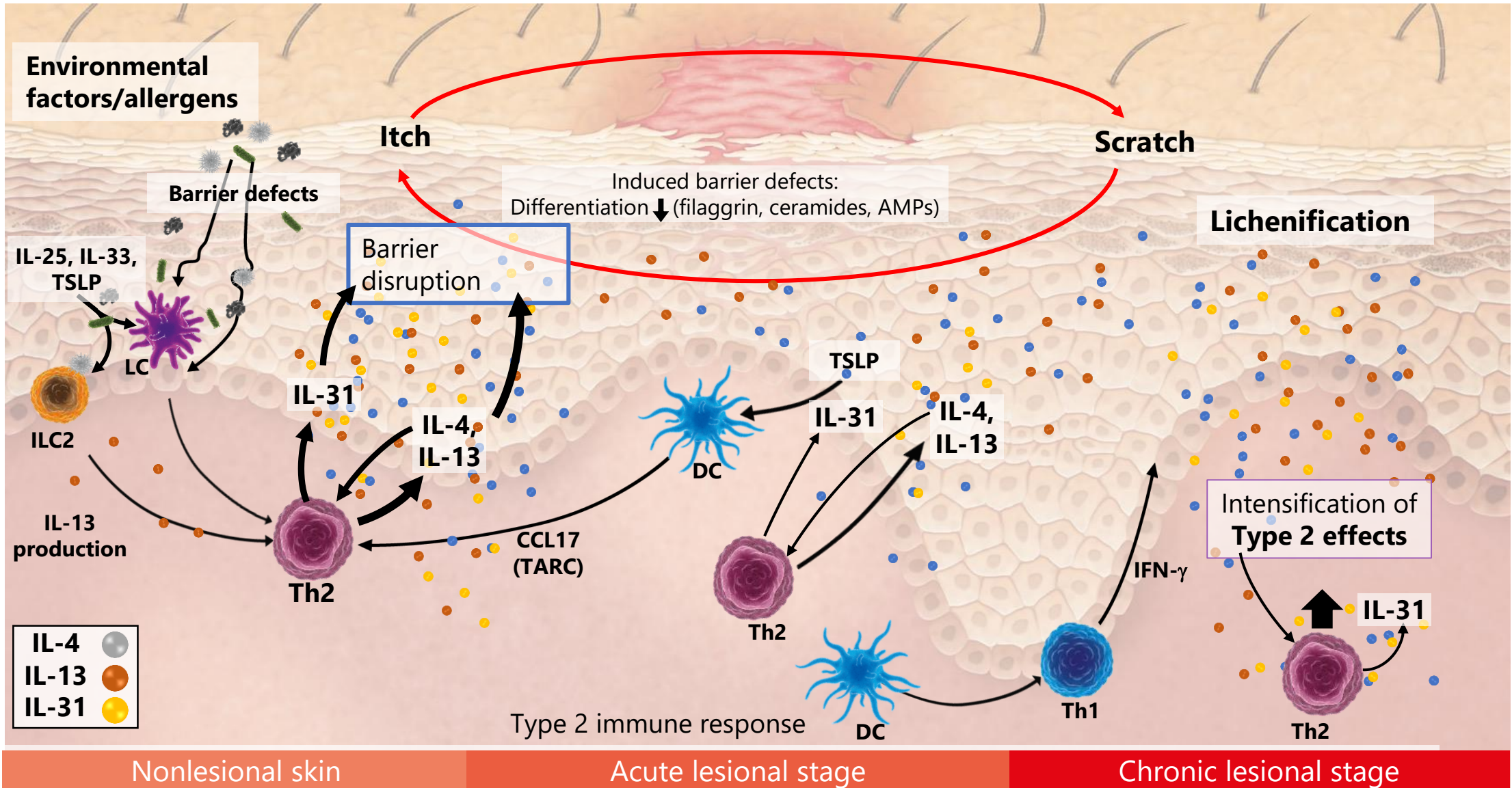
- Mental Health Issues appear more common
- Anxiety and Depression with More Severe Disease
 - Approximately 1 in 5 adults: meet “diagnostic criteria” for major depression
- Attention Deficit Hyperactivity Disorder (ADHD) in younger children
- SLEEP DISTURBANCE and FATIGUE!

The Impact of Atopic Dermatitis



1. Simpson EL, et al. J Am Acad Dermatol. 2016;74:491–98. 2. Brunner PM, et al. J Invest Dermatol. 2017;137:18–25. 3. Simpson EL. Curr Dermatol Rep. 2012;1:29–38. 4. Strom MA, et al. Br J Dermatol. 2016;175:920–29. 5. Schmitt J, et al. J Allergy Clin Immunol. 2016;137:130–136. 6. Silverberg JI, et al. J Allergy Clin Immunol. 2015;135:721–728.e6. 7. Silverberg JI. Allergy 2015;70:1300–1308. 8. Whiteley J, et al. Curr Med Res Opin. 2016;1–7. 9. Simpson E, et al. EADV 2016. Poster P0301. 10. Drucker AM, et al. J Invest Dermatol. 2017;137:26–30. 11. Zuberbier T, et al. J Allergy Clin Immunol. 2006;118:226–232

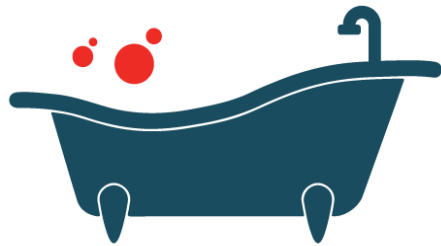
Pathogenesis of AD: Barrier, Inflammation



WHAT THERAPIES ARE USED, AND WHAT
CLINICAL NEEDS ARE THERE?

First Interventions: “Good Skin Care”

Bathing and moisturizing



Topical Corticosteroids

Traditional mainstay of therapy for Atopic Dermatitis

- Anti-inflammatory
- Used for acute flare management
- Intermittently for maintenance therapy

SIDE EFFECTS, CONCERNS, PHOBIAS:

- SYSTEMIC ABSORPTION
 - Concern with higher potency agents
- Local effects
 - Skin atrophy
 - Striae (stretch marks): irreversible complication

Topical Calcineurin Inhibitors

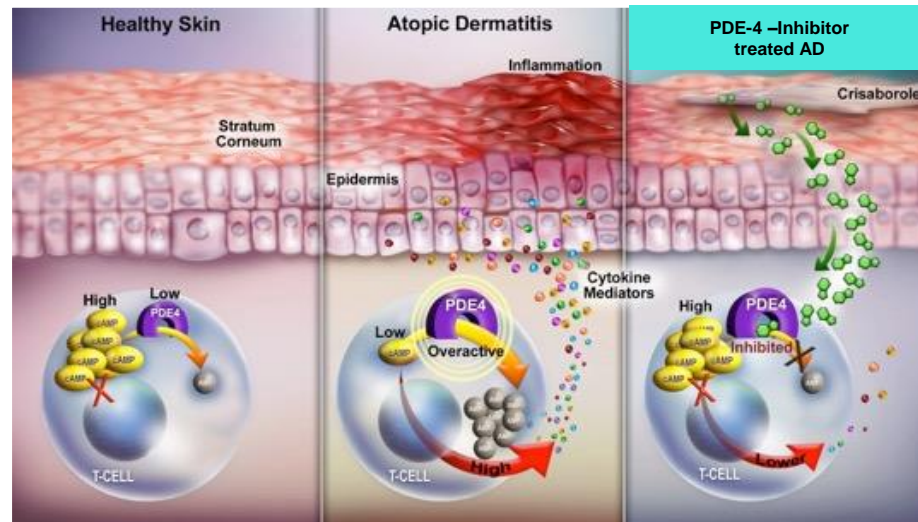
Anti-inflammatory medicines

Non-steroids

- Second-line therapy
 - Tacrolimus
 - Pimecrolimus
- Fair to good efficacy: mild, moderate, severe AD
- Stinging and burning may occur

Crisaborole 2% ointment: Topical PDE-4 Inhibitor

- Approved for patients ≥ 3 months old with mild-to-moderate atopic dermatitis
- Approved dosing: apply a thin layer twice daily to affected areas
- Appears Safe; Limited Efficacy
- Stinging and burning in subset of patients



Paller AS, et al. *J Am Acad Dermatol.* 2016;75(3):494-503
Eichenfield LF et al. *J Am Acad Dermatol.* 2017

Systemic Therapy: Moderate to Severe AD

- ‘Traditional Systemics:’
 - MTX most commonly used in US, but uncommonly used. Not approved
- Evolving area of Clinical Work..
- Dupilumab is first up of new agents
 - Phototherapy
 - Cyclosporine
 - Azathioprine
 - Methotrexate
 - Mycophenolate mofetil
 - Systemic steroids (Approved, not advised)
 - Dupilumab (FDA Approved 12+)

Evolving Systemic Agents

Systemic Agents

- Oral JAK Inhibitors
- IL-13 Blockers (Lebrikizumab; Tralokinumab)
- Nemolizumab (IL31 blocker)

Multiple Others!

Integrating the New with the Standard

- Mild to Moderate Disease: MOST ECZEMA!
- **TOPICALS** WILL STILL HANDLE MOST DISEASE!
- There IS GREAT NEED for a more potent, well tolerated non-steroid topical agent that is anti-inflammatory and effectively decreases itch!
- The market is still relatively untouched! Much work to be done to establish long term disease control!



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TRUE-AD1 & TRUE-AD2 PHASE 3 DATA

JIM LEE, MD, PHD



Presented at the 2nd Annual Revolutionizing Atopic Dermatitis Conference
April 5, 2020; Chicago, IL

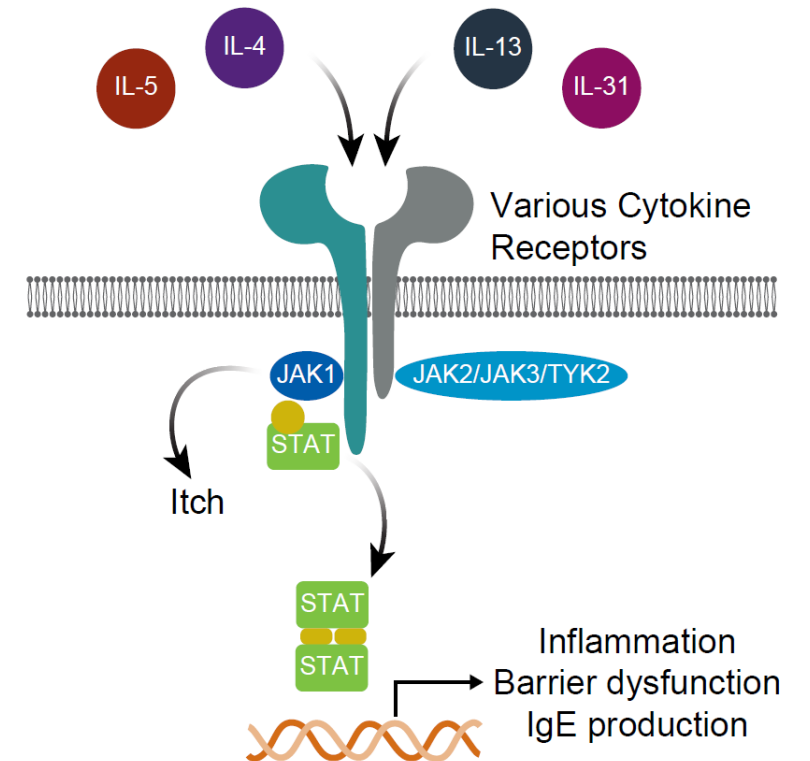
Efficacy and Safety of Ruxolitinib Cream for the Treatment of Atopic Dermatitis: Results From Two Phase 3, Randomized, Double-Blind Studies

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Michael E. Kuligowski, MD, PhD, MBA,⁵ May Venturanza, MD,⁵ Kang Sun, PhD,⁵
Eric Simpson, MD⁶

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ATOPIC DERMATITIS AND JAK SIGNALING

- Atopic dermatitis (AD) is a chronic, inflammatory skin disease that greatly impacts patients' quality of life^{1,2}
- JAKs modulate inflammatory cytokines involved in the pathogenesis of AD³ and may also directly modulate itch⁴
- Ruxolitinib (RUX) is a potent, selective inhibitor of JAK1 and JAK2⁵
- In a phase 2 study (NCT03011892), RUX cream provided dose-dependent efficacy in patients with AD, with no notable adverse events⁶
- **Objective:** To report efficacy and safety of RUX cream in patients with AD in two phase 3 studies (TRuE-AD1 [NCT03745638] and TRuE-AD2 [NCT03745651])



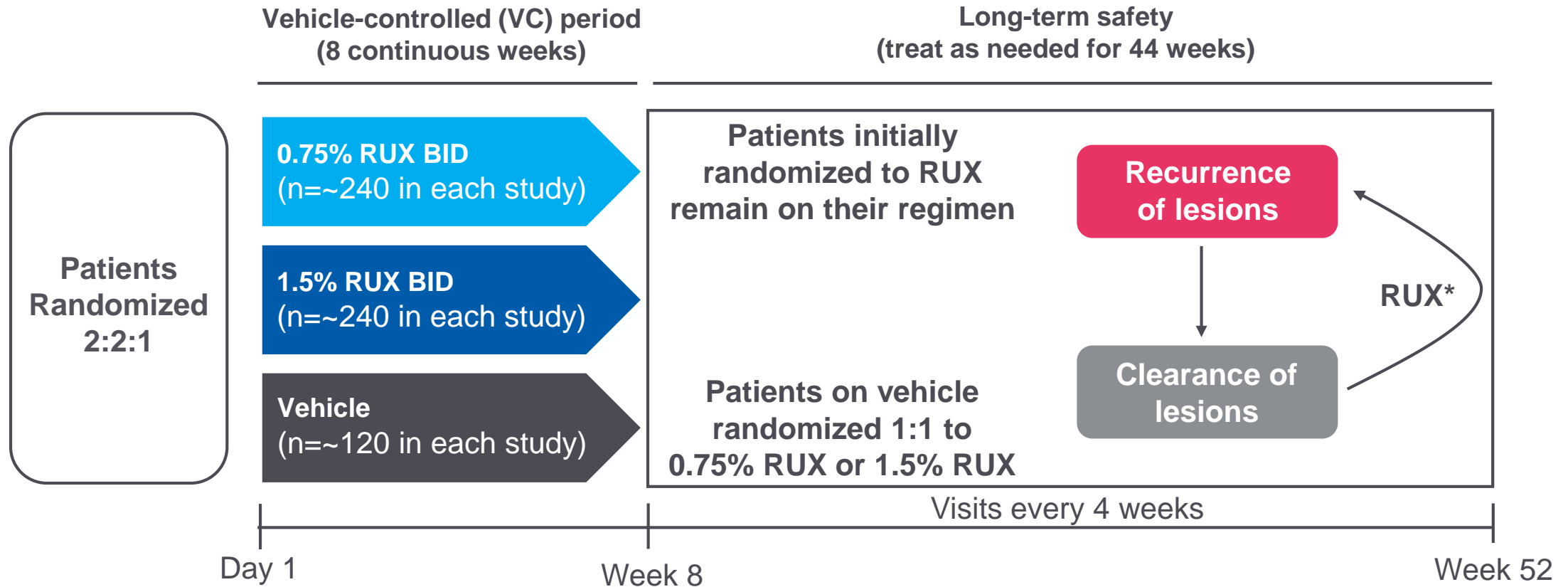
Reproduced from Kim BS, et al. 2020.⁶ Use of this figure is permitted under the terms of the Creative Commons Attribution 4.0 International License (<https://creativecommons.org/licenses/by-nc-nd/4.0/>); no changes to this figure have been made.



IgE, immunoglobulin E; IL, interleukin; JAK, Janus kinase; STAT, signal transducer and activator of transcription; TYK2, tyrosine kinase 2.

1. Wei W, et al. *J Dermatol.* 2018;45(2):150-157; 2. Silverberg JI, et al. *Ann Allergy Asthma Immunol.* 2018;121(3):340-347; 3. Bao L, et al. *JAKSTAT.* 2013;2(3):e24137; 4. Oetjen LK, et al. *Cell.* 2017;171(1):217-228; 5. Quintas-Cardama A, et al. *Blood.* 2010;115(15):3109-3117; 6. Kim BS, et al. *J Allergy Clin Immunol.* 2020;145(2):572-582.

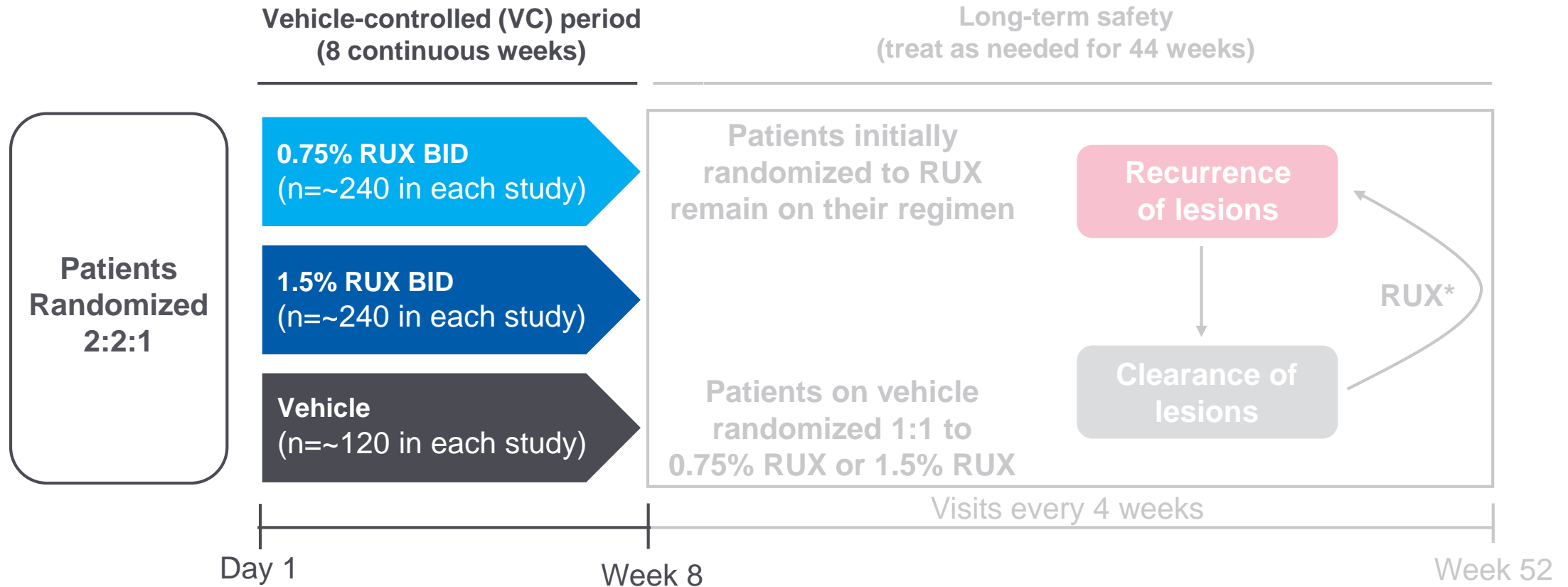
STUDY DESIGN



BID, twice daily; BSA, body surface area.

* Patients will self-evaluate recurrence of lesions between study visits and will treat lesions with active AD ($\leq 20\%$ BSA). If lesions clear between study visits, patients will stop treatment 3 days after lesion disappearance. If new lesions are extensive or appear in new areas, patients will contact the investigator to determine if an additional visit is needed.

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STUDY ENDPOINTS

- Primary Endpoint
 - Proportion of patients achieving IGA-TS (score of 0/1 with ≥ 2 -grade improvement from baseline) at Week 8
- Main Secondary Endpoints
 - Proportion of patients achieving $\geq 75\%$ improvement in EASI score vs baseline (EASI-75)
 - Proportion of patients with a ≥ 4 -point improvement in itch NRS score from baseline to Week 8



ELIGIBILITY CRITERIA

- Key Inclusion Criteria

- Patients aged ≥ 12 years with AD ≥ 2 years
- IGA score of 2 or 3
- 3%–20% affected BSA

- Key Exclusion Criteria

- Unstable course of AD
- Other types of eczema
- Immunocompromised status
- Any serious illness/medical condition that could interfere with study conduct, interpretation of data, or patients' well-being
- Use of AD systemic therapies during the washout period and during the study
- Use of AD topical therapies (except bland emollients) during the washout period and during the study

PATIENT DEMOGRAPHICS

Distribution of baseline demographics was similar across treatment groups

| | TRuE-AD1 | | | TRuE-AD2 | | |
|------------------------|--------------------|----------------------|---------------------|--------------------|----------------------|---------------------|
| | Vehicle (n=126) | 0.75% RUX (n=252) | 1.5% RUX (n=253) | Vehicle (n=124) | 0.75% RUX (n=248) | 1.5% RUX (n=246) |
| Age, median (range), y | 31.5 (12–82) | 34.0 (12–85) | 30.0 (12–77) | 37.5 (12–82) | 33.0 (12–81) | 32.0 (12–85) |
| 12–17, n (%) | 23 (18.3) | 53 (21.0) | 47 (18.6) | 22 (17.7) | 55 (22.2) | 45 (18.3) |
| ≥18, n (%) | 103 (81.7) | 199 (79.0) | 206 (81.4) | 102 (82.3) | 193 (77.8) | 201 (81.7) |
| Female, n (%) | 79 (62.7) | 154 (61.1) | 158 (62.5) | 80 (64.5) | 150 (60.5) | 150 (61.0) |
| Race, n (%)* | | | | | | |
| White | 85 (67.5) | 171 (67.9) | 175 (69.2) | 84 (67.7) | 174 (70.2) | 178 (72.4) |
| Black | 29 (23.0) | 55 (21.8) | 56 (22.1) | 32 (25.8) | 63 (25.4) | 57 (23.2) |
| Other | 12 (9.5) | 26 (10.3) | 21 (8.3) | 8 (6.5) | 11 (4.4) | 11 (4.5) |
| Region, n (%) | | | | | | |
| North America | 88 (69.8) | 176 (69.8) | 176 (69.6) | 84 (67.7) | 166 (66.9) | 165 (67.1) |
| Europe | 38 (30.2) | 76 (30.2) | 77 (30.4) | 40 (32.3) | 82 (33.1) | 81 (32.9) |



* Data missing from 1 patient in the 1.5% RUX group in TRuE-AD1.

PATIENT CLINICAL CHARACTERISTICS

Distribution of baseline clinical characteristics was similar across treatment groups

| | TRuE-AD1 | | | TRuE-AD2 | | |
|---|--------------------|----------------------|---------------------|--------------------|----------------------|---------------------|
| | Vehicle (n=126) | 0.75% RUX (n=252) | 1.5% RUX (n=253) | Vehicle (n=124) | 0.75% RUX (n=248) | 1.5% RUX (n=246) |
| BSA, mean ± SD, % | 9.2±5.1 | 9.9±5.4 | 9.3±5.2 | 10.1±5.8 | 10.1±5.3 | 9.9±5.4 |
| Baseline EASI, mean ± SD | 7.4±4.3 | 8.2±4.8 | 7.9±4.6 | 8.2±5.2 | 8.1±5.0 | 7.8±4.9 |
| Baseline IGA, n (%) | | | | | | |
| 2 | 31 (24.6) | 61 (24.2) | 60 (23.7) | 33 (26.6) | 64 (25.8) | 63 (25.6) |
| 3 | 95 (75.4) | 191 (75.8) | 193 (76.3) | 91 (73.4) | 184 (74.2) | 183 (74.4) |
| Itch NRS score, mean ± SD | 5.1±2.5 | 5.1±2.3 | 5.2±2.5 | 5.1±2.4 | 5.2±2.5 | 4.9±2.5 |
| Itch NRS score ≥4, n (%) | 78 (61.9) | 156 (61.9) | 161 (63.6) | 81 (65.3) | 168 (67.7) | 154 (62.6) |
| Duration of disease, median (range), y | 17.9 (1.9–79.1) | 14.1 (1.0–68.8) | 16.0 (0–69.2) | 15.9 (0.8–70.7) | 15.9 (0.1–68.6) | 16.6 (0–68.8) |
| Facial involvement, n (%) | 52 (41.3) | 112 (44.4) | 118 (46.6) | 41 (33.1) | 83 (33.5) | 79 (32.1) |

SAFETY

- RUX cream was well tolerated and not associated with clinically significant application site reactions
- All treatment-related TEAEs were mild or moderate in severity
- No TEAEs suggestive of a relationship to systemic exposure were observed

| | TRuE-AD1 | | | TRuE-AD2 | | |
|---|--------------------|----------------------|---------------------|--------------------|----------------------|---------------------|
| | Vehicle (n=126) | 0.75% RUX (n=252) | 1.5% RUX (n=253) | Vehicle (n=124) | 0.75% RUX (n=248) | 1.5% RUX (n=246) |
| Patients with TEAE, n (%) | 44 (34.9) | 74 (29.4) | 73 (28.9) | 40 (32.3) | 73 (29.4) | 58 (23.6) |
| Treatment-related TEAE, n (%) | 16 (12.7) | 15 (6.0) | 14 (5.5) | 12 (9.7) | 8 (3.2) | 11 (4.5) |
| Most common treatment-related TEAEs, n (%) | | | | | | |
| Application site burning | 2 (1.6) | 0 | 2 (0.8) | 8 (6.5) | 2 (0.8) | 2 (0.8) |
| Application site pruritus | 2 (1.6) | 2 (0.8) | 0 | 4 (3.2) | 2 (0.8) | 0 |
| Pruritus | 2 (1.6) | 2 (0.8) | 1 (0.4) | 0 | 0 | 0 |
| Discontinuation due to a TEAE, n (%) | 5 (4.0) | 3 (1.2) | 3 (1.2) | 3 (2.4) | 1 (0.4) | 0 |
| Serious TEAE, n (%)* | 2 (1.6) | 1 (0.4) | 2 (0.8) | 0 | 3 (1.2) | 1 (0.4) |



TEAE, treatment-emergent adverse event.
* No serious TEAEs were related to RUX treatment.

PATIENT DISPOSITION DURING THE VC PERIOD

TRuE-AD1*

Randomized: n=631

Discontinued: n=73 (11.6%)

- Withdrawal by patient: n=31 (4.9%)
- Lost to follow-up: n=24 (3.8%)
- Adverse event: n=10 (1.6%)
- Protocol deviation: n=2 (0.3%)
- Lack of efficacy: n=2 (0.3%)
- Noncompliance with study drug: n=1 (0.2%)
- Physician decision: n=1 (0.2%)
- Pregnancy: n=1 (0.2%)
- Other: n=1 (0.2%)

Completed: n=558
(88.4%)

TRuE-AD2†

Randomized: n=618

Discontinued: n=57 (9.2%)

- Withdrawal by patient: n=24 (3.9%)
- Lost to follow-up: n=20 (3.2%)
- Adverse event: n=5 (0.8%)
- Protocol deviation: n=3 (0.5%)
- Lack of efficacy: n=1 (0.2%)
- Noncompliance with study drug: n=1 (0.2%)
- Physician decision: n=1 (0.2%)
- Pregnancy: n=0
- Other: n=2 (0.3%)

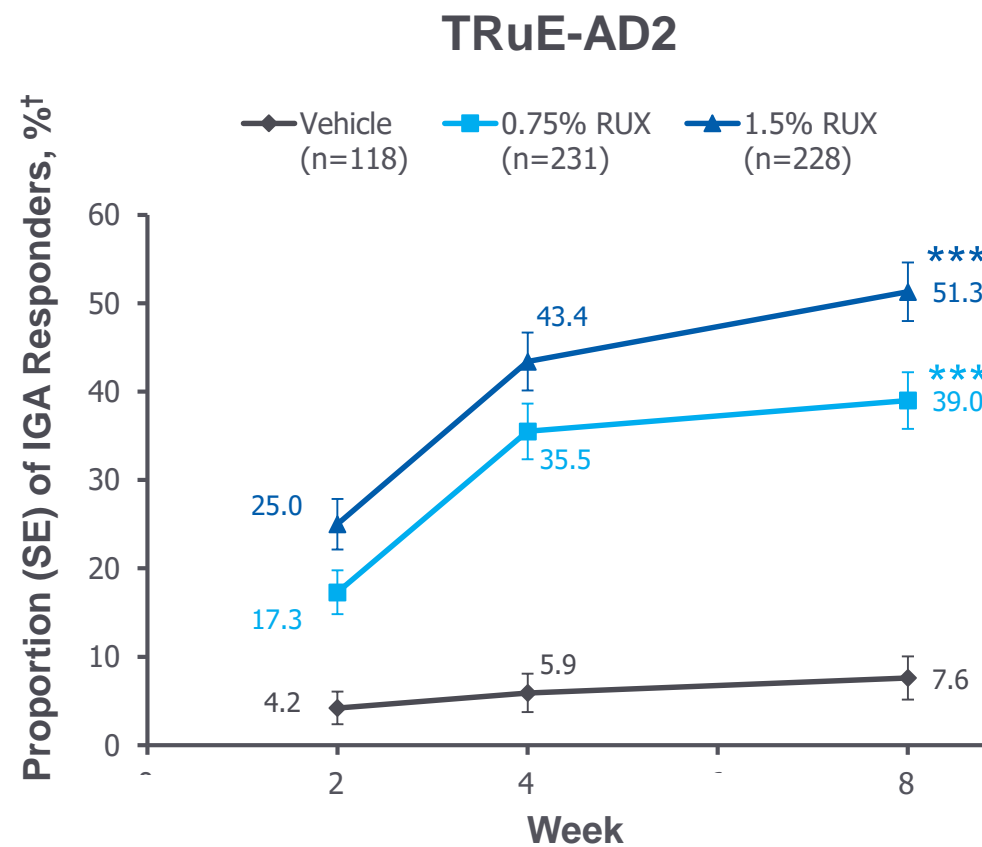
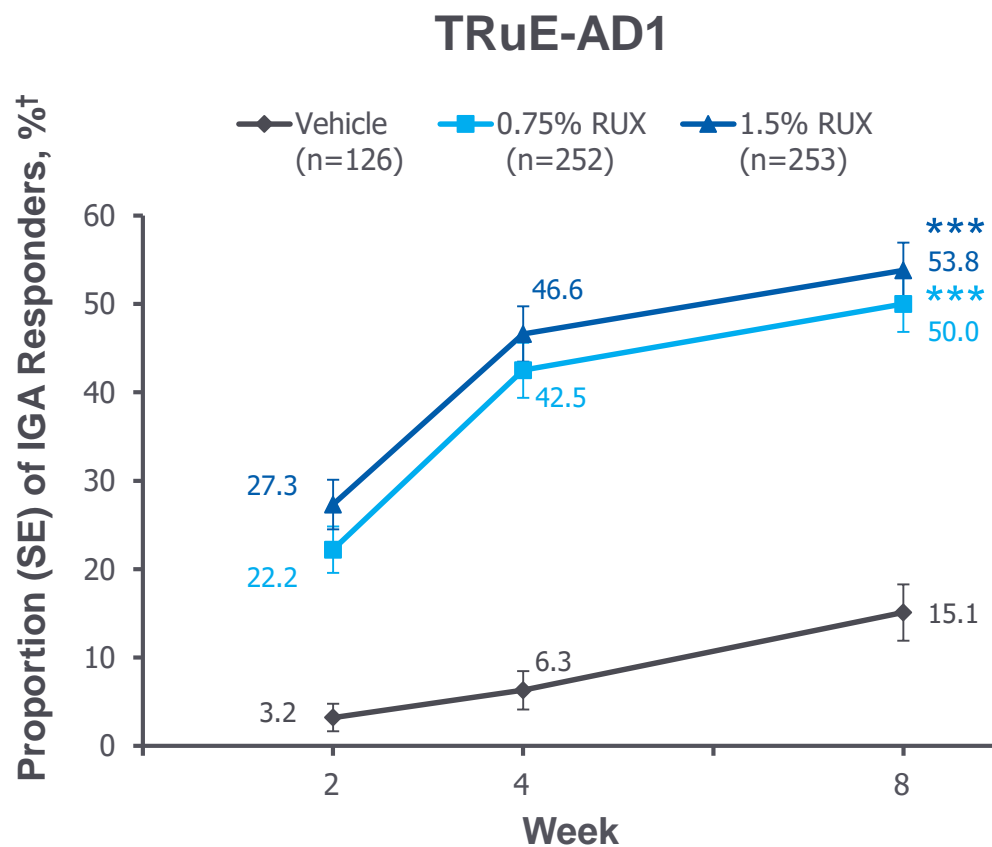
Completed: n=561
(90.8%)



* All randomized patients were included in the efficacy analysis. † Efficacy population consisted of 577 patients (vehicle, n=118; 0.75% RUX, n=231; 1.5% RUX, n=228).

PROPORTION OF PATIENTS WITH IGA-TS

Significantly more patients treated with RUX cream regimens vs vehicle demonstrated IGA-TS (primary endpoint); responses were time and dose dependent



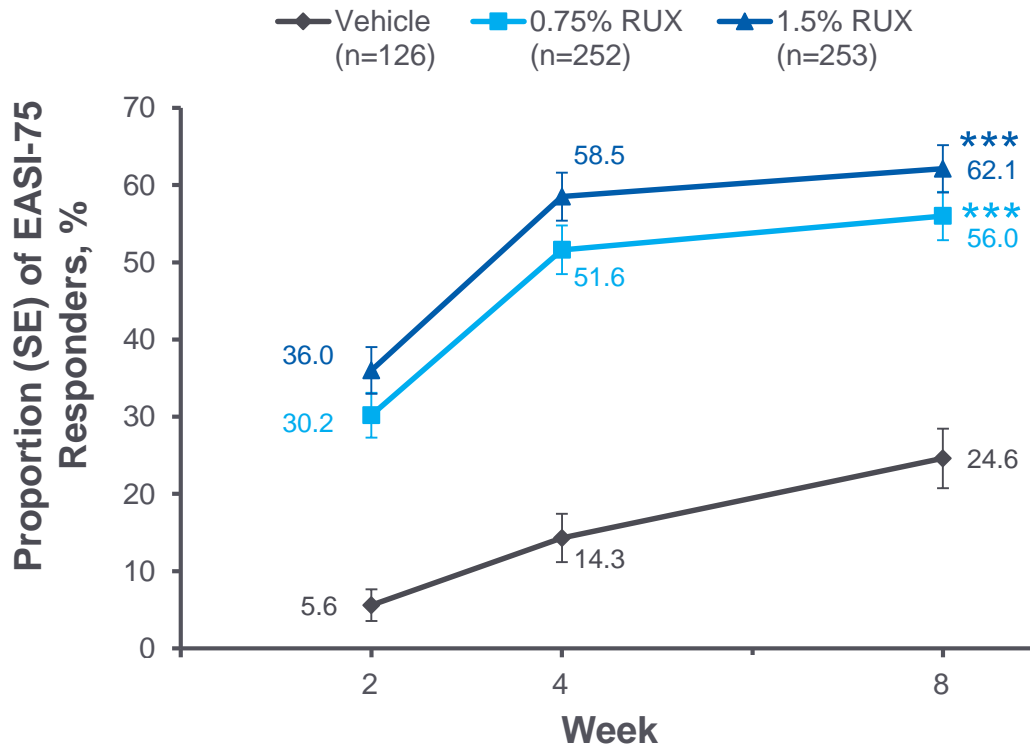
SE, standard error.
*** $P < 0.0001$.

† Defined as patients achieving an IGA score of 0 or 1 with an improvement of ≥ 2 points from baseline.

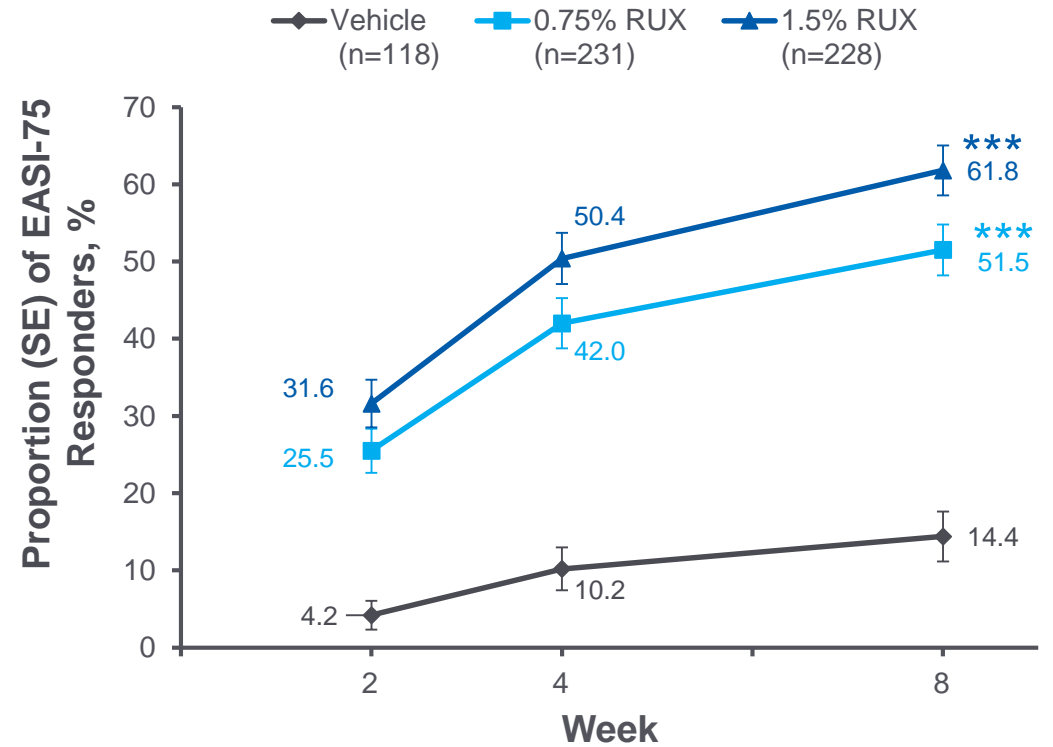
PROPORTION OF PATIENTS ACHIEVING EASI-75

Significantly more patients treated with RUX cream achieved EASI-75 vs vehicle; responses were time and dose dependent

TRuE-AD1



TRuE-AD2

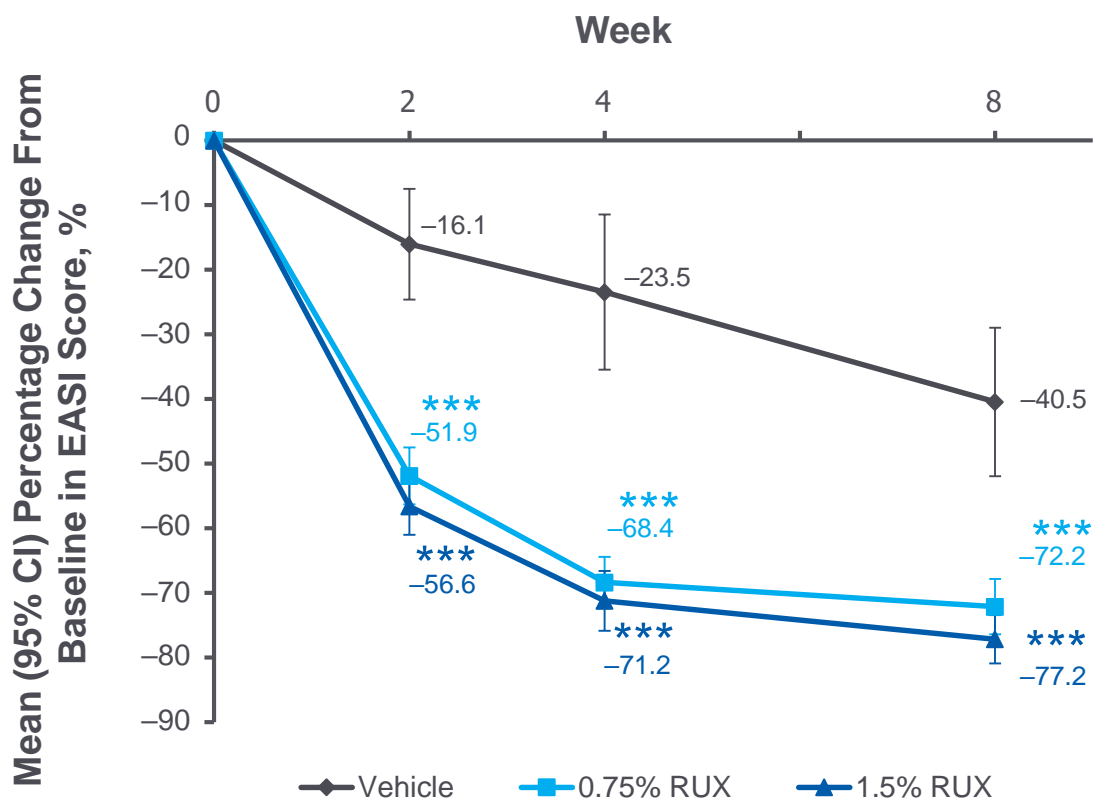


*** $P < 0.0001$.

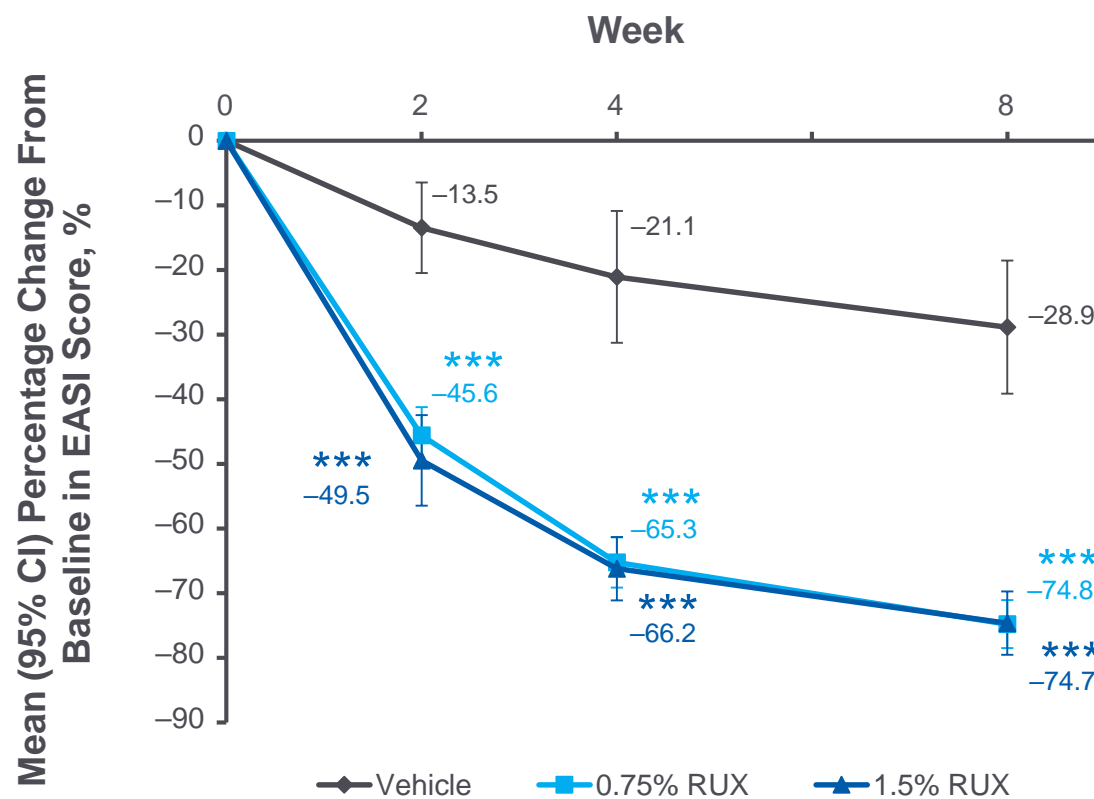
EASI PERCENTAGE CHANGE FROM BASELINE

Both strengths of RUX cream showed greater improvement in mean percentage change in EASI scores vs vehicle; statistical significance was observed at Week 2 and later

TRuE-AD1



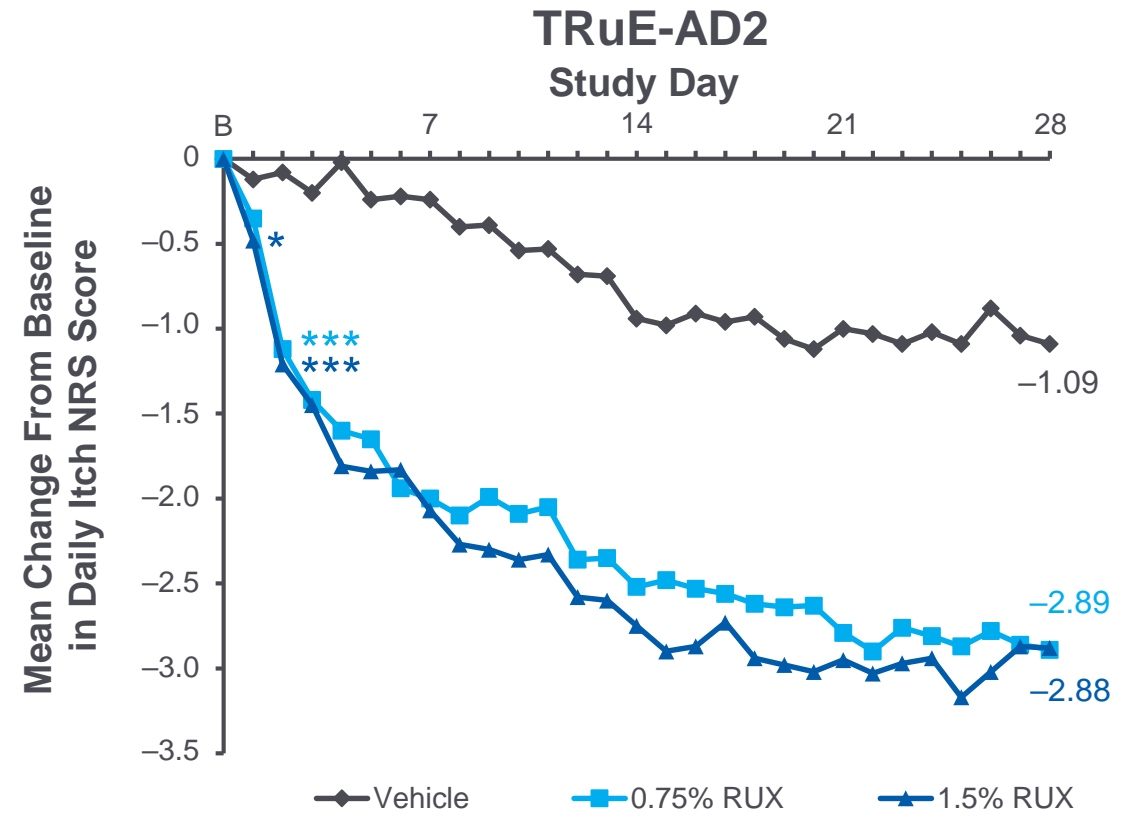
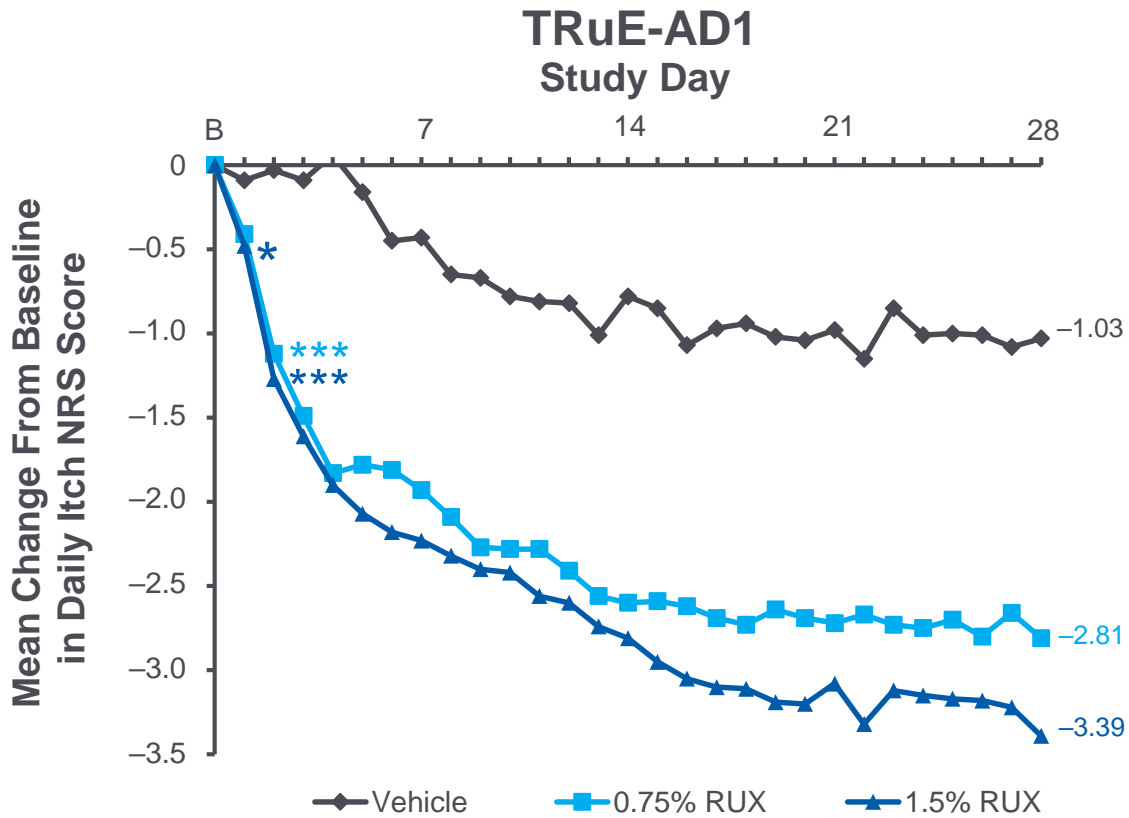
TRuE-AD2



*** P < 0.0001.

CHANGE FROM BASELINE IN DAILY ITCH NRS SCORE

Significantly greater itch reductions in itch NRS scores were observed within 12 hours of the first application of RUX cream (1.5%; $P < 0.05$) vs vehicle

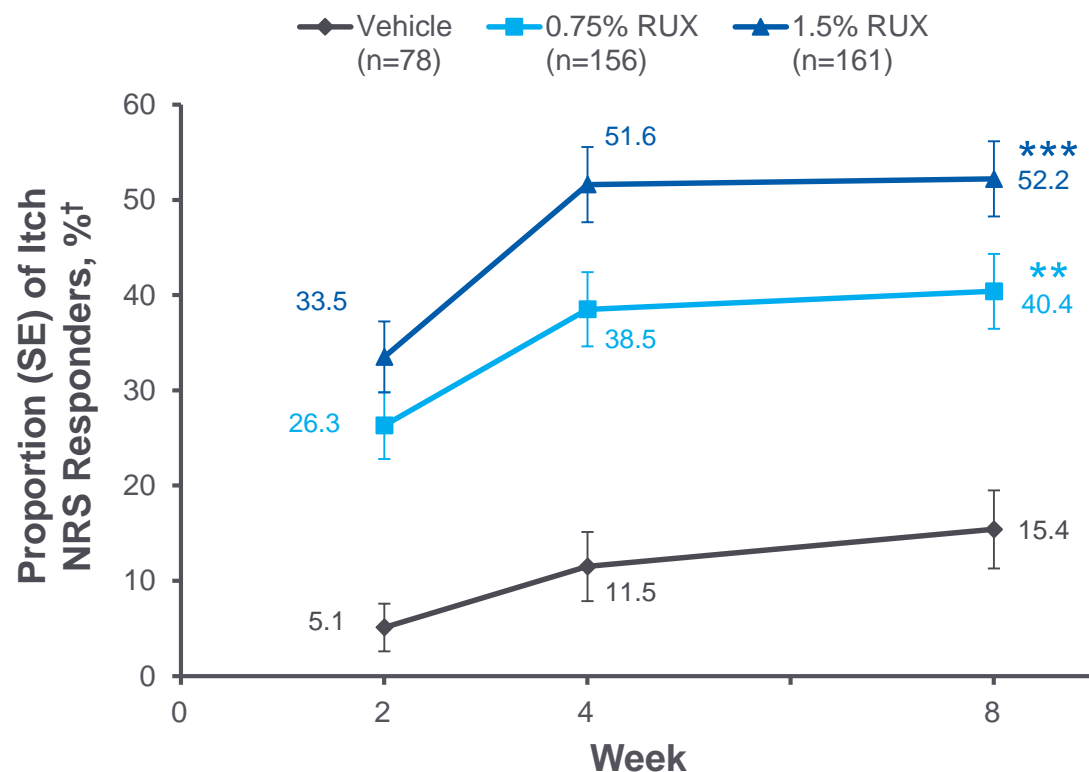


B, baseline.
* $P < 0.05$; *** $P < 0.0001$.

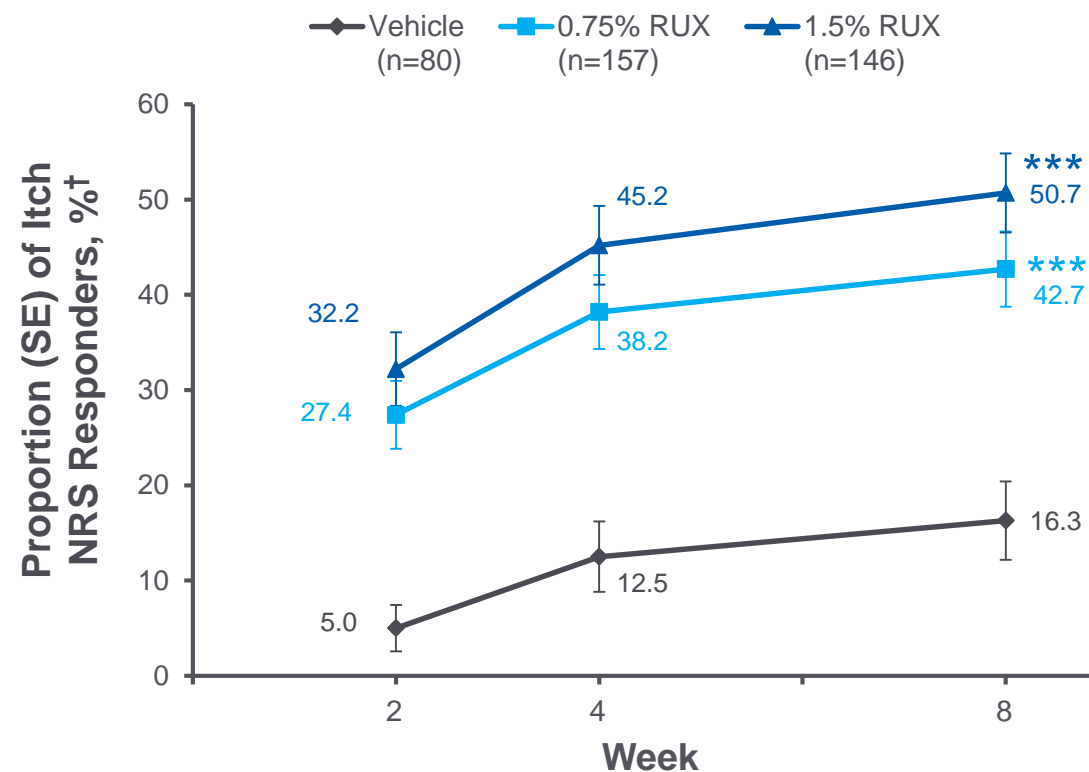
≥4-POINT IMPROVEMENT IN ITCH NRS

Significantly more patients treated with RUX cream demonstrated clinically meaningful reduction in itch (≥4-point improvement in itch NRS) vs vehicle

TRuE-AD1



TRuE-AD2



** $P < 0.001$; *** $P < 0.0001$.

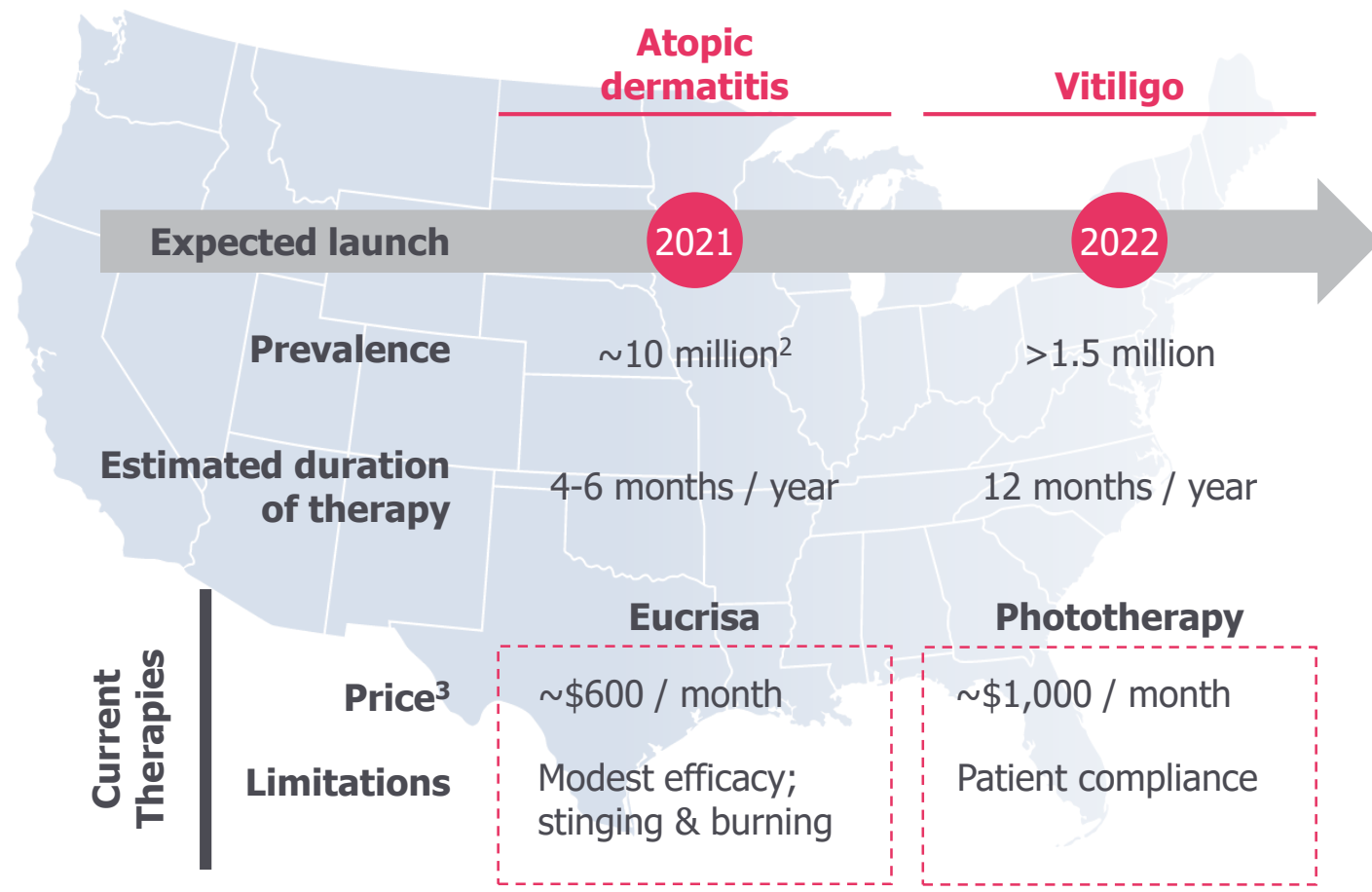
† Patients in the analysis had an NRS score ≥ 4 at baseline.

CONCLUSIONS

- Application of ruxolitinib cream brought about rapid (within 12 hours of initiation of therapy), substantial, and sustained reduction in itch
- Ruxolitinib cream showed superior efficacy vs vehicle in IGA-TS, EASI-75, and ≥ 4 -point reduction in itch NRS score in these two phase 3 studies
- Ruxolitinib cream demonstrated a dual mode of action: antipruritic and anti-inflammatory
- No notable safety findings (either local or systemic) were associated with treatment, including on sensitive skin areas
- The successful outcomes of TRuE-AD1 and TRuE-AD2 support the potential of ruxolitinib cream as an effective and well-tolerated topical treatment for patients with AD

INCYTE TO COMMERCIALIZE RUX CREAM IN THE U.S.¹

NEAR-TERM OPPORTUNITY TO FURTHER DIVERSIFY REVENUE



Planning for commercial success

Targeting key prescribers

- 8,000 medical dermatologists

Dedicated division planned

- Commercial deployment expected in 2021
- ~150 field-based FTE's



1. If approved by FDA
 2. Diagnosed and treated mild/moderate AD patients (aged ≥ 12 years)
 3. Estimated WAC price of Eucria ~\$600 per 60g tube; estimated cost of phototherapy based on lower price of two reimbursement codes (price can be as much as \$20-25,000 per year, reimbursed price generally significantly lower)



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