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OPZELURA™

(ruxolitinib) cream

FDA Approval Call

SEPTEMBER 22, 2021



FORWARD LOOKING STATEMENTS

Except for the historical information set forth herein, the matters set forth in this presentation, including statements regarding whether or when Opzelura™ might provide a successful treatment option for patients with atopic dermatitis; the Company's plans to commercialize Opzelura; the likelihood that HCPs will prescribe Opzelura; the potential market opportunity presented by Opzelura, including the Company's estimate of what "peak sales" could look like; the Company's expectations with regard to payer coverage for Opzelura and patient interest in and access to Opzelura; and the Company's plans and/or expectations with respect to the future development and/or commercialization of ruxolitinib cream, including with respect to additional indications, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; 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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials supply chain and other third-party providers and development and discovery operations; determinations made by the FDA or other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.



HERVÉ HOPPENOT

CHIEF EXECUTIVE OFFICER, INCYTE



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OPZELURA™ FIRST AND ONLY TOPICAL JAK INHIBITOR APPROVED FOR MILD TO MODERATE ATOPIC DERMATITIS

Opzelura™ (ruxolitinib) cream 1.5%

- ✓ Unique breakthrough treatment for millions of patients with uncontrolled mild to moderate AD
- ✓ Achieves skin clearance in >50% of patients at Week 8
- ✓ Provides substantial itch relief
- ✓ Long-term disease control with intermittent use
- ✓ Non-steroidal cream formulation



JIM LEE, M.D., Ph.D.

**GROUP VICE PRESIDENT
HEAD OF INFLAMMATION/AUTOIMMUNITY (IAI)**



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OPZELURA U.S. LABEL: FOR PATIENTS 12 YEARS AND OLDER WITH INADEQUATELY CONTROLLED AD

Indications and Usage

OPZELURA is a Janus kinase (JAK) inhibitor indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Dosage and Administration

Apply a thin layer of **OPZELURA** twice daily to affected areas of up to 20% body surface area. Do not use more than 60 grams per week.



OPZELURA U.S. LABEL: SKIN CLEARANCE AND ITCH REDUCTION ACHIEVED IN MAJORITY OF PATIENTS

Efficacy Results at Week 8 in Subjects with Atopic Dermatitis (Trials 1 and 2)

	Trial 1			Trial 2		
	OPZELURA (n=253)	Vehicle (n=126)	Treatment Difference (95% CI)	OPZELURA (n=228)	Vehicle (n=118)	Treatment Difference (95% CI)
IGA-TS¹	53.8% (136/253)	15.1% (19/126)	38.9% (30.3%, 47.4%)	51.3% (117/228)	7.6% (9/118)	44.1% (36.2%, 52.0%)
Itch NRS (≥4 point reduction) (n/N)²	52.2% (84/161)	15.4% (12/78)	36.7% (25.5%, 48.0%)	50.7% (74/146)	16.3% (13/80)	35.8% (24.4%, 47.2%)

Opzelura is the **first and only approved topical product** to demonstrate a statistically significant 4-point or greater reduction in itch



1. Defined as an IGA score of 0 or 1 with a ≥ 2-grade improvement from baseline
2. N= subjects with a baseline Itch NRS score ≥4.

OPZELURA U.S. LABEL: AE PROFILE SIMILAR TO VEHICLE

Adverse Reactions Occurring in $\geq 1\%$ of Subjects Treated with OPZELURA for Atopic Dermatitis through Week 8 in Trials 1 and 2

Adverse Reaction	OPZELURA (N=499) n (%)	Vehicle (N=250) n (%)
<i>Subjects with any TEAE*</i>	<i>132 (27)</i>	<i>83 (33)</i>
Nasopharyngitis	13 (3)	2 (1)
Bronchitis	4 (1)	0 (0)
Ear infection	4 (1)	0 (0)
Eosinophil count increased	4 (1)	0 (0)
Urticaria	4 (1)	0 (0)
Diarrhea	3 (1)	1 (< 1)
Folliculitis	3 (1)	0 (0)
Tonsillitis	3 (1)	0 (0)
Rhinorrhea	3 (1)	1 (< 1)

Adverse reactions that occurred in Trials 1 and 2 in < 1% of subjects in the OPZELURA group and none in the vehicle group were: neutropenia, allergic conjunctivitis, pyrexia, seasonal allergy, herpes zoster, otitis externa, Staphylococcal infection, and acneiform dermatitis.



*TEAE = treatment emergent adverse events
Opzelura [package insert] Wilmington, DE. Incyte Corporation: 2021

OPZELURA U.S. LABEL: BOXED WARNING FOR JAK INHIBITORS

Boxed Warning*

SERIOUS INFECTIONS

Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death [see *Warnings and Precautions (5.1) and Adverse Reactions (6.1)*].

Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease.
- Invasive fungal infections, including candidiasis and pneumocystosis.
- Bacterial, viral, and other infections due to opportunistic pathogens.

Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled. The risks and benefits of treatment with OPZELURA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OPZELURA [see *Warnings and Precautions (5.1)*].

MORTALITY

Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with oral Janus kinase inhibitors for inflammatory conditions [see *Warnings and Precautions (5.2)*].

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions [see *Warnings and Precautions (5.3)*].

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions [see *Warnings and Precautions (5.4)*].

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis has been observed at an increased incidence in patients treated with oral Janus kinase inhibitors for inflammatory conditions compared to placebo. Many of these adverse reactions were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated [see *Warnings and Precautions (5.5)*].

Class boxed warning follows FDA review of oral JAK inhibitors treating inflammatory conditions



*Full details regarding warnings is available in the Opzelura prescribing information.

1. Opzelura [package insert] Wilmington, DE. Incyte Corporation: 2021
2. MACE includes cardiovascular death, myocardial infarction, and stroke)
3. Thrombosis includes deep venous thrombosis, pulmonary embolism, and arterial thrombosis.

OPZELURA: INCIDENCE OF EVENTS DURING VEHICLE CONTROL RANDOMIZED TRIAL PERIOD WAS EITHER LOW OR ZERO

Randomized Portion of Trial (8 wks)

	Opzelura 1.5% n (%)	Vehicle n (%)
	n=499	n=250
Serious Infections	0	0
Mortality	0	0
Malignancies	1 (0.2%)	1 (0.4%)
➤ Lymphomas	0	0
➤ NMSC	1 (0.2%)	0
MACE	1 (0.2%)	0
Thrombosis	0	0

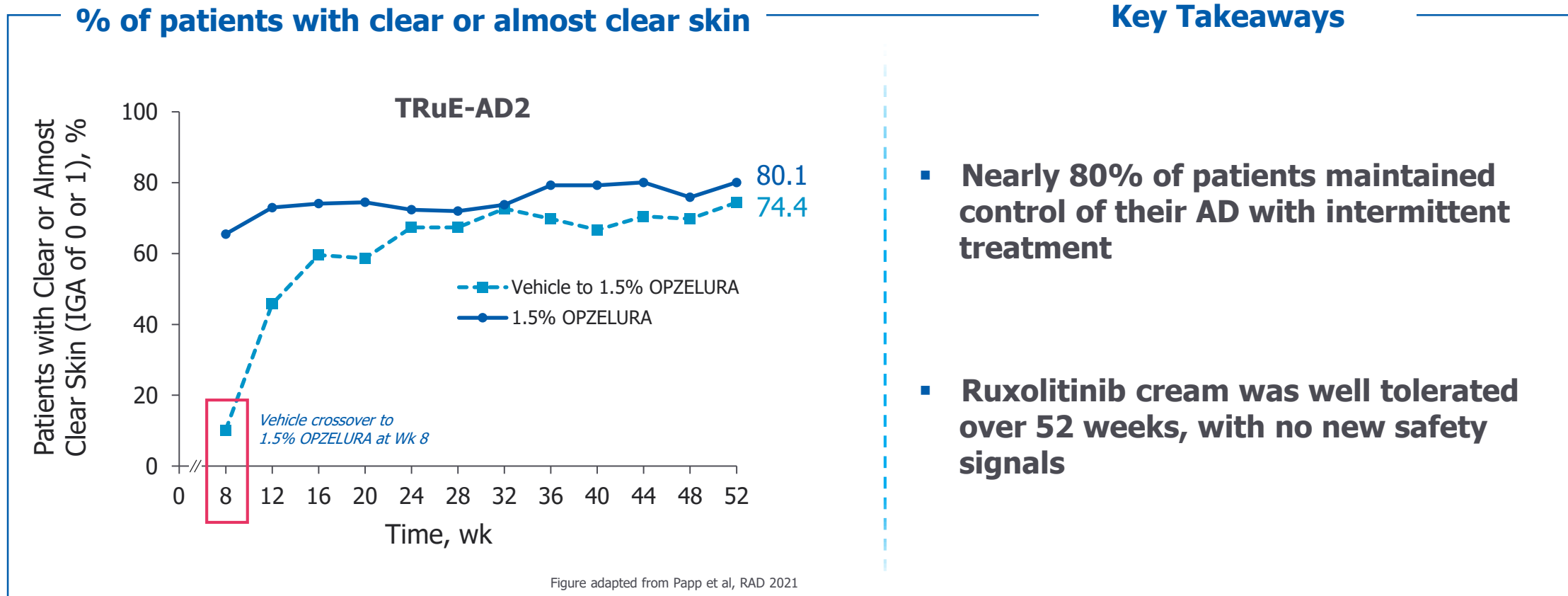


*Full details regarding warnings is available in the Opzelura prescribing information. NMSC = non-melanoma skin cancers.

1. Opzelura [package insert] Wilmington, DE. Incyte Corporation: 2021
2. MACE includes cardiovascular death, myocardial infarction, and stroke)
3. Thrombosis includes deep venous thrombosis, pulmonary embolism, and arterial thrombosis.

BEYOND THE APPROVED INDICATION AND CURRENT LABEL

EFFECTIVE LONG-TERM DISEASE CONTROL REGARDLESS OF PRIOR MEDICATION OR SEVERITY OF AD



Atopic Dermatitis: Treatment Landscape and Clinical Need!

Lawrence F. Eichenfield, M.D.

Distinguished Professor of Dermatology and Pediatrics

Vice Chair, Department of Dermatology

Chief, Pediatric and Adolescent Dermatology

University of California, San Diego

Rady Children's Hospital, San Diego



**UNIVERSITY of CALIFORNIA, SAN DIEGO
MEDICAL CENTER**



The “short story” of atopic dermatitis

- High prevalence
 - 10 to 20% in children; 7% in adults²
- Significant disease burden, comorbidities^{1–3,5}
- Variable course and severity
 - Different triggers in different patients
 - Mixed immune pathogenesis in many patients
- Despite availability of different topical therapies, high unmet need for faster amelioration of itch and long term disease control

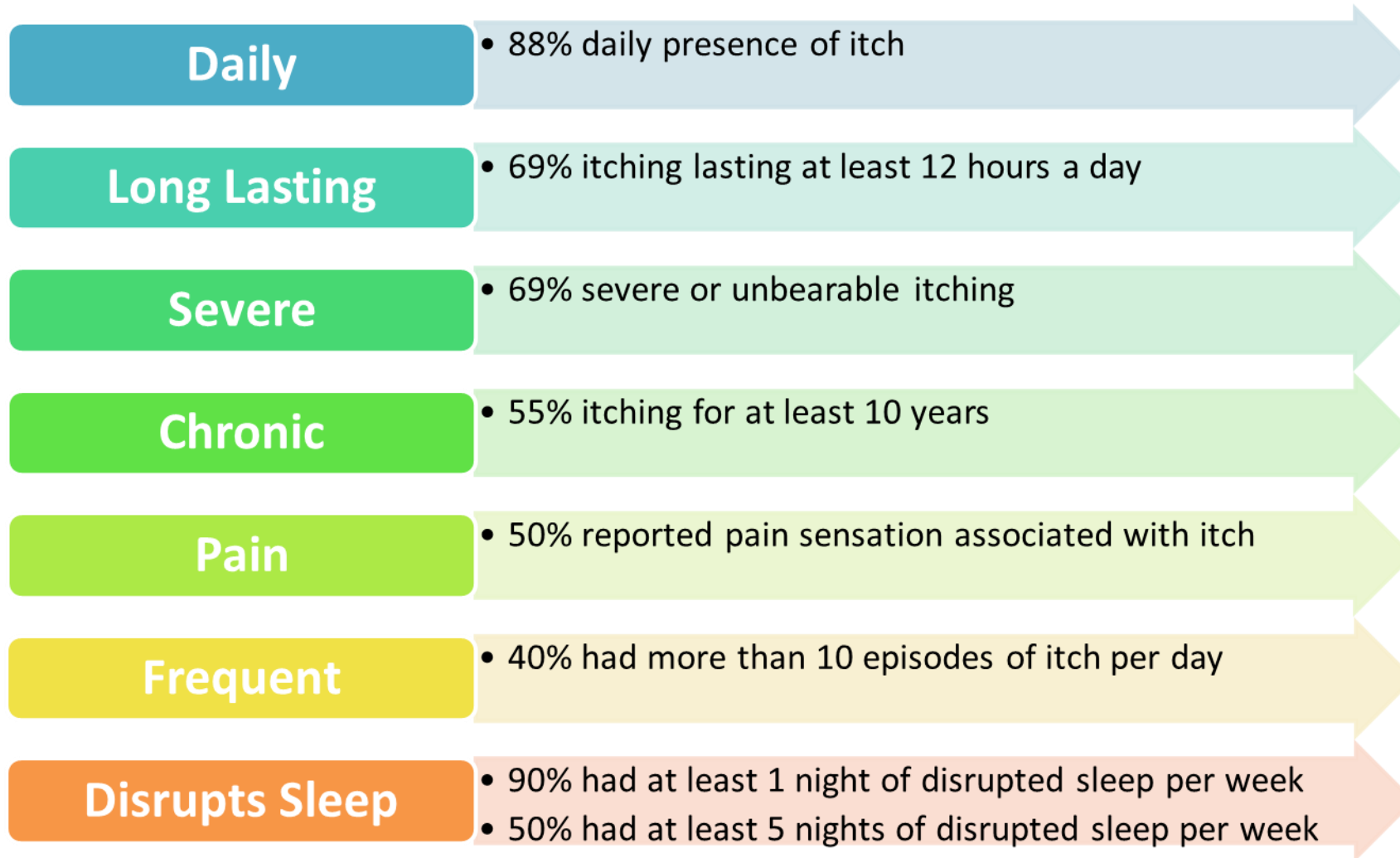


Manifestations of Atopic Dermatitis

- ECZEMATOUS RASHES
 - Oozing, crusting, scaling
 - Redness, swelling, heat and pain
- ITCH!!!!!!
- DRY SKIN/XEROSIS
 - Barrier dysfunction (inherent in some, worse with inflammation)
- INFLAMMATION: Some you can see, some you can't!
- SECONDARY INFECTIONS: Staph, Herpes
- CHRONICITY: Recurrent; or Persistent; Plus flares



Itch: Most Common Burden



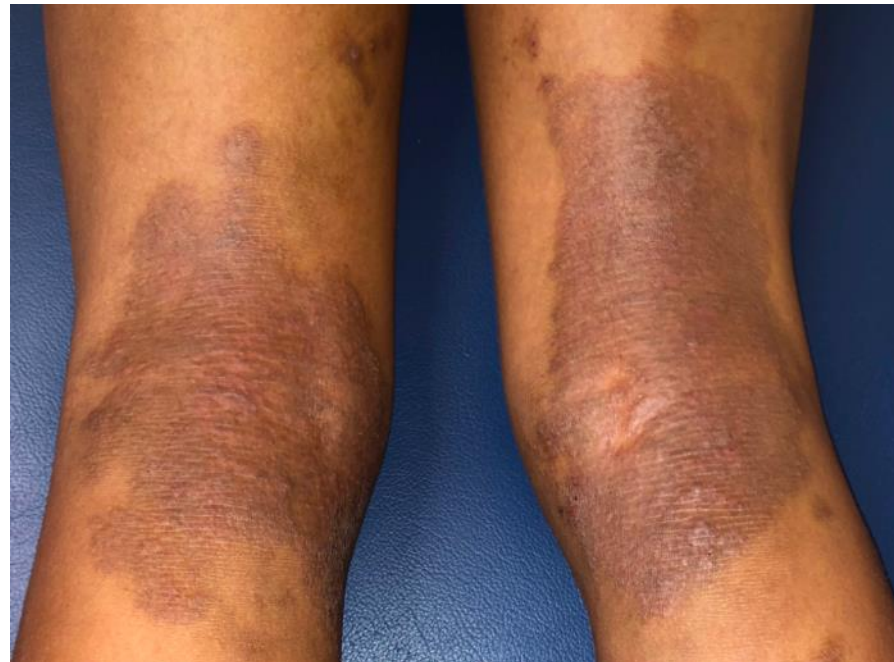




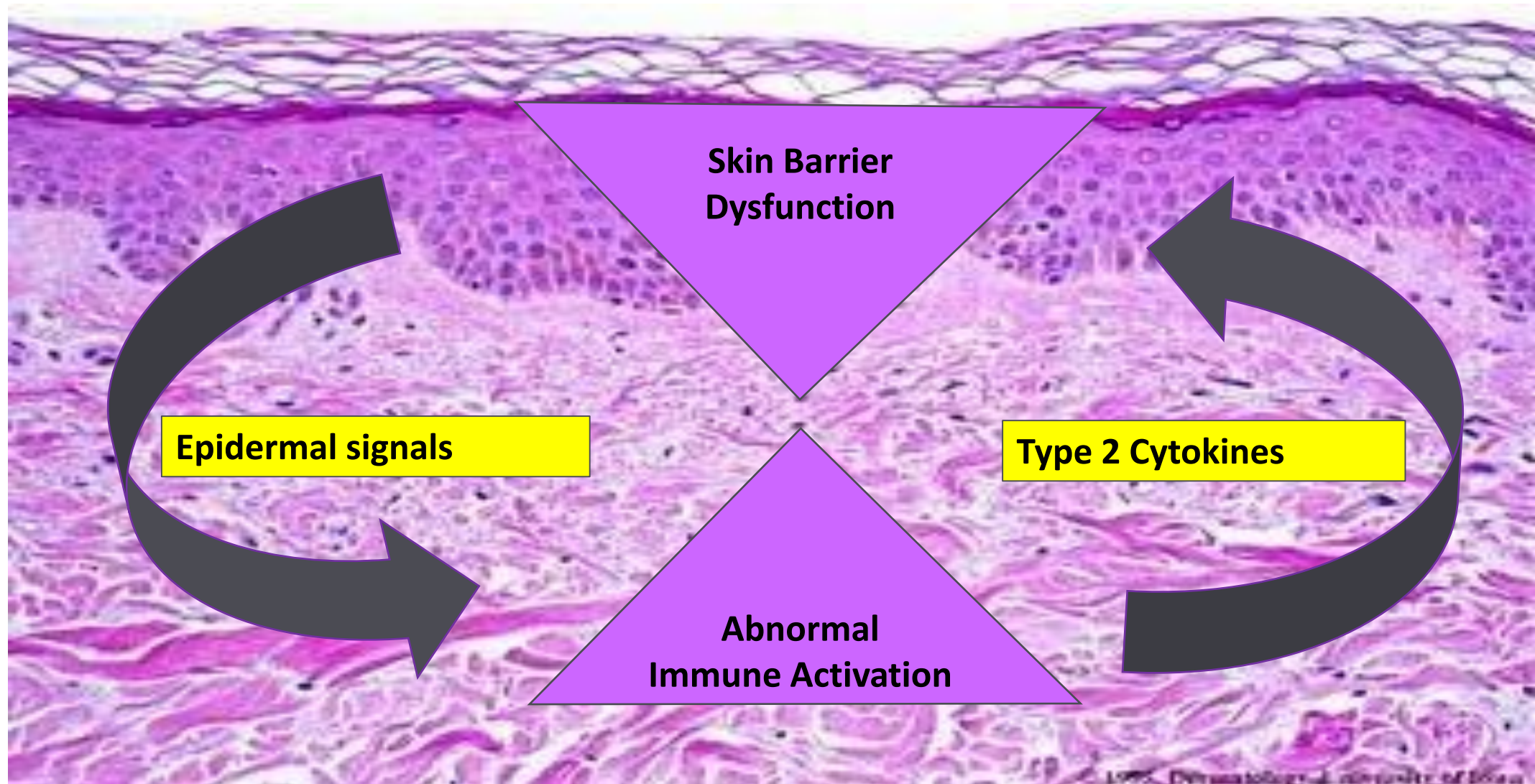




Discoloration



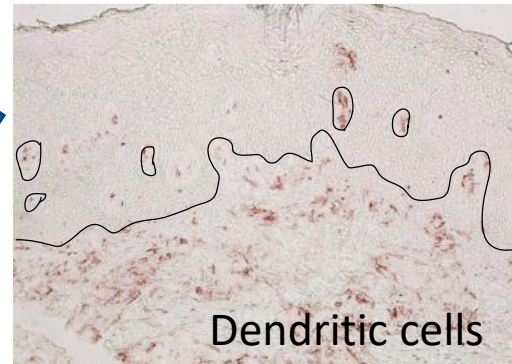
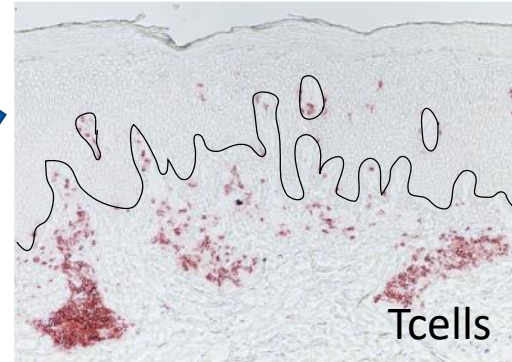
AD Pathogenesis



Immune Activation in Atopic Dermatitis



Lesional AD



Th2

IL-4, 5, 10, 13, 31

Th1

IFN-g, IFN-a

Th17

IL-17

Others

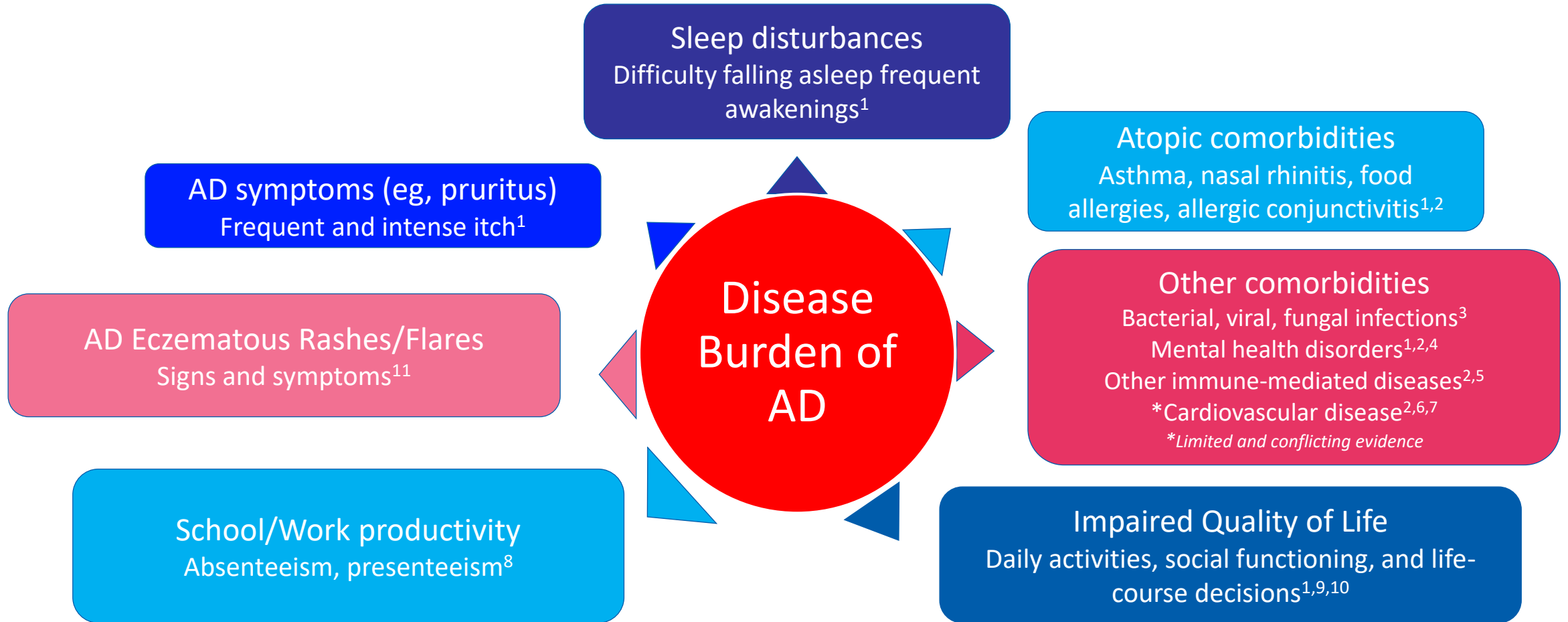
IL-22, TSLP, IFN-a, IL-17C

1. Gittler JK, et al. *J Allergy Clin Immunol.* 2012;130(6):1344-1354.

Atopic Dermatitis: Eczema

Why does it matter?

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

Impact: Patients and Families!

- Emotional distress: embarrassment, social isolation
- Depression; Anxiety
- Adolescents: teasing, bullying
- Limitations in activities: sports and swimming due to lesions and fear of triggers¹
- Sleep disturbance resulting in difficulty performing at school and work
- Family impact: Exhaustion in caregivers/spouses



1. Drucker AM, et al. *J Invest Dermatol*. 2017;137(1):26-30. 2. Lewis-Jones S. *Int J Clin Pract*. 2006;60(8):984-992. 3. Strom MA, et al. *Br J Dermatol*. 2016;175(5):920-929. 4. Moore K, et al. *Br J Dermatol*. 2006;154:514-518. 5. Lifschitz C. *Ann Nutr Metab*. 2015;66(Suppl 1):34-40. 6. Ramirez FD, et al. *JAMA Dermatol*. 2019 Mar 20. doi:10.1001/jamadermatol.2018.5641; Patel KR, et al. *J Am Acad Dermatol*. 2019;80(2):402-410.

Basics of Management of Atopic Dermatitis

Skin Care

- Gentle bathing; Frequent moisturizer use!

Trigger Avoidance

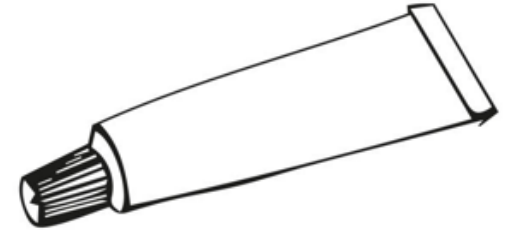
- Common irritants; Allergens if proven
- **Adjuvants:** Antihistamines, Bleach baths

INFLAMMATION:

- *Topical corticosteroids* first line (range in strength from 1-2200x)
- Alternatives:
 - *Topical calcineurin inhibitors* (tacrolimus, pimecrolimus)
 - *PDE-4 Inhibitor:* Crisaborole

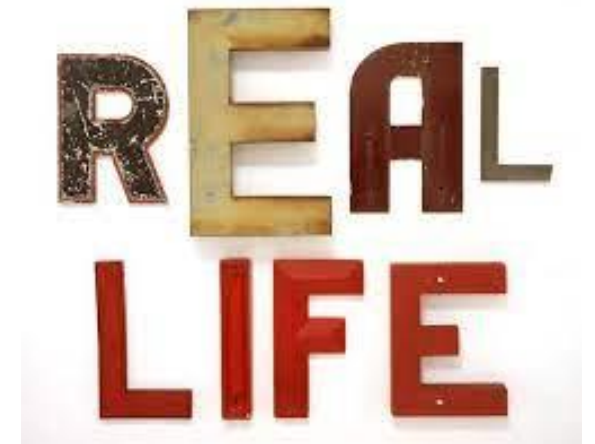
BEYOND Topicals: Moderate to severe refractory:

- Dupilumab (biologic, IL4R α -blocker); Oral corticosteroids; Traditional immunosuppressives; Phototherapy



Atopic Dermatitis: Real Life Issues

- Much undertreatment!
- Steroid and TCI phobia
- PDE-4s: Tolerance issues
- EFFICACY of non-steroids is limited!
- Long term disease control is the goal! But we often aren't meeting that goal consistently



Most patients are going to be treated with topical medications, with systemics restricted to more severe patients!

How will Opzelura fit into Eczema Care?

- It will have broad application due to its:
 - Robust efficacy and safety data
 - Impact on itch
 - Consistent effects across populations
 - Unmet need



TODD EDWARDS

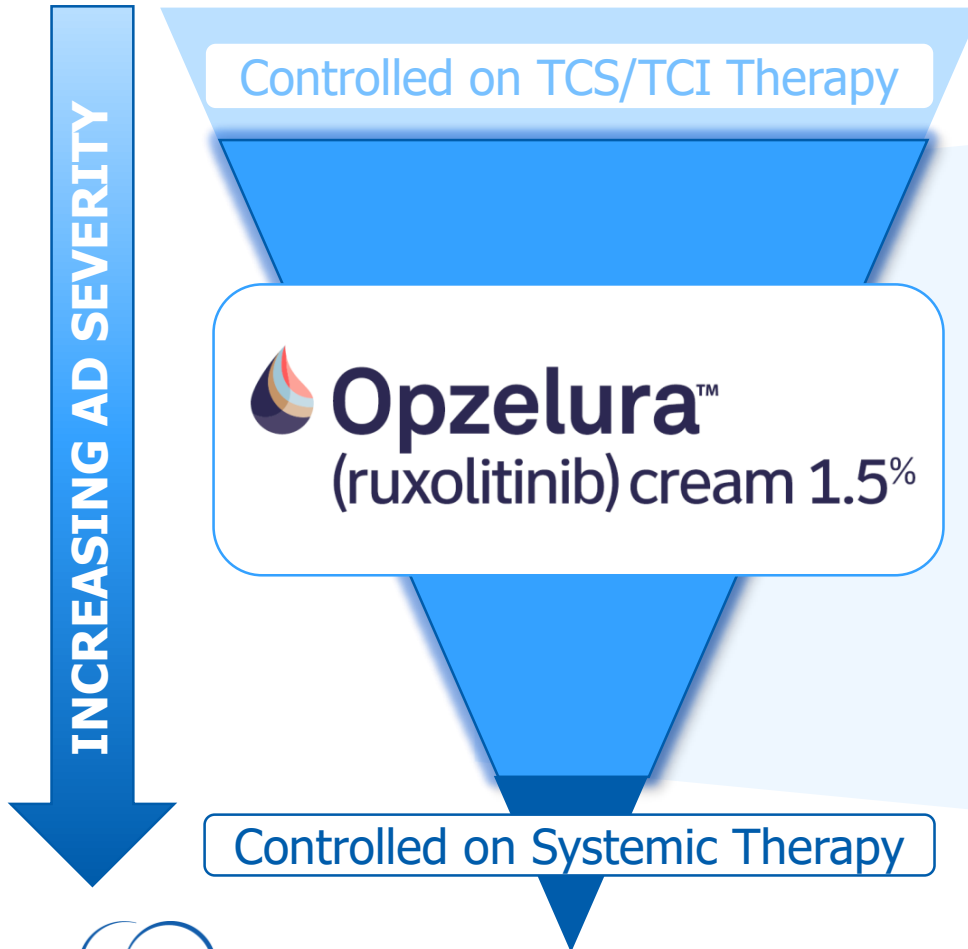
**GROUP VICE PRESIDENT
BUSINESS UNIT HEAD OF IAI**



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SIGNIFICANT UNMET NEED IN ATOPIC DERMATITIS

5.5 million AD patients in the US (≥ 12 years) are drug-treated



Patients with AD seeking alternatives¹

- ~**22%** of **patients** report their AD is well controlled with current treatment
- >**40%** of AD **patients** experience flares at least 1x or more per week
- ~**50%** of **patients** experienced cracks in their skin due to AD in the last month

HCPs eager to try Opzelura²

- 85%** of **HCPs** indicate they are likely to prescribe Opzelura
- 15%** reduction in prescribing as a result of class box warning



5.5 million patients in the US 12 years of age and older with mild to severe AD are drug-treated.

Figure for illustrative purposes only. 1. Based on survey with AD patients (n~650); 2. Based on Demand Assessment Study with dermatologists (n=165), July 2020

UNIQUE PRODUCT PROFILE TO ADDRESS PATIENT NEEDS

Unmet Need

Symptom relief top priority for HCPs and Patients, with particular emphasis on itch relief

Desire for a safe and well-tolerated non-steroidal topical

Emphasis on ability to provide adequate skin clearance

 **Opzelura™**
(ruxolitinib) cream 1.5%

Statistically significant reductions in Itch NRS4

Non-steroidal cream formulation

IGA clearance achieved (0 or 1) in 54% of patients at Week 8

LAUNCH TEAM WITH DEEP EXPERIENCE IN DERMATOLOGY



- **150 reps and MSLs** recruited from dermatology companies
- Experts in specialty **payer account management**



- **High-performing representatives**
- **100%** of reps have pre-existing dermatology relationships
- **10** average years of dermatology sales experience



- **Fully trained** reps with comprehensive curriculum
- **High scientific proficiency** of field reps



Top performers

80% of reps were ranked in the **90th** percentile at previous companies

BRINGING HIGHLY DIFFERENTIATED PRODUCT TO HCPS

MAJORITY OF ATOPIC DERMATITIS PRESCRIPTIONS WRITTEN BY DERMATOLOGISTS

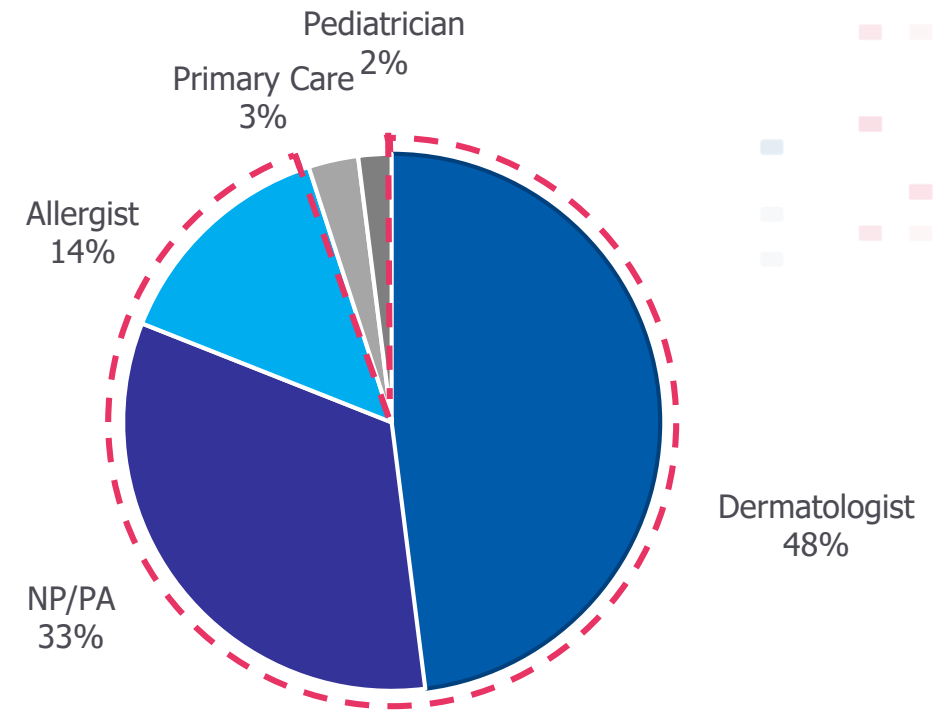
Specialty focused targeting

- ~11,000 Dermatologists, NP/PAs & high priority Allergists
 - Top 20% of Dermatologists, NP/PAs and Allergists write 78% of market prescriptions¹ for AD

Driving awareness with HCPs

- Many offices are open for in-person promotion
- Compelling itch/scratch/inflammation efficacy messaging
- Topical formulation aligned with preferred treatment approach
- Comprehensive and targeted multi-channel marketing reach

AD Scripts by Provider¹



1. Market basket includes Dupixent, Eucrisa, Protopic, Elidel, Pimecrolimus, and Tacrolimus.

PROJECTED LAUNCH PAYER COVERAGE

THREE GPO/PBMS CONTROL NEARLY 80% (195M LIVES) OF COMMERCIALY INSURED PATIENTS

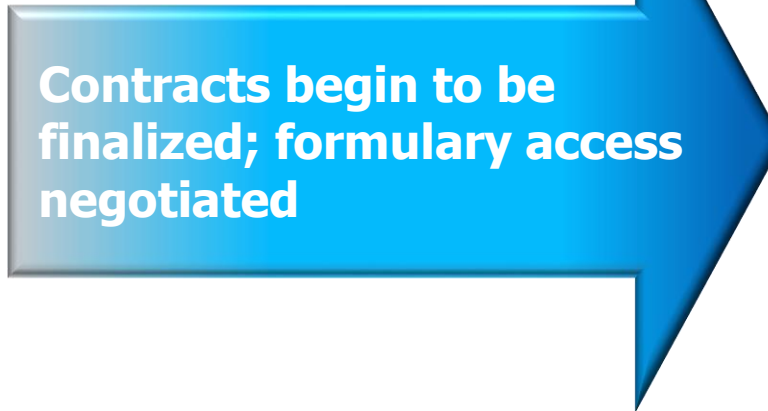
At Launch



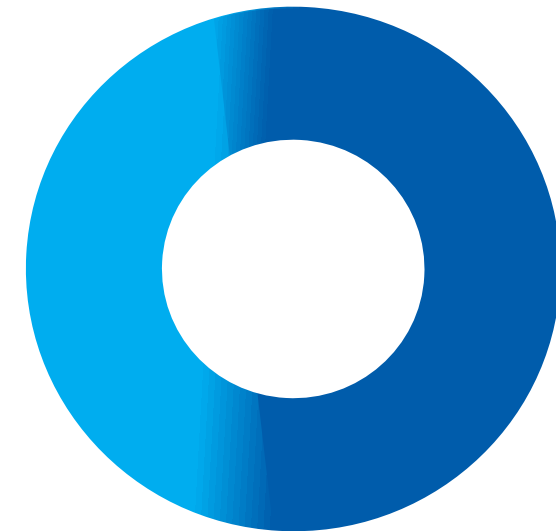
■ New-To-Market Block:
IncyteCARES coverage program

■ Variable Access Upon Launch:
Prior authorization and co-pay programs

Q4'21



Starting in Q1'22



■ New-To-Market Blocks Removed:
Streamlined access

■ Addition to formularies:
Negotiated access



REDUCING BARRIERS TO PATIENT ACCESS

PATIENT SUPPORT THROUGH INCYTECARES



Covered patients



Copay Savings Program



NDC blocked patients



Denial Conversion Program



Patients with a prior authorization or appeal



CoverMyMeds



Uninsured or Underinsured patients



Patient Assistance Program



MARKET OPPORTUNITY

ADDRESSING A SIGNIFICANT UNMET NEED

~5.5 million¹

PATIENTS

3-4 tubes
used per year

SCRIPTS

\$1.5+ BILLION

**PEAK SALES ESTIMATE FOR
AD IN THE US**



1. 5.5 million drug-treated AD patients 12+ years or older in the US

HERVÉ HOPPENOT

CHIEF EXECUTIVE OFFICER, INCYTE



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CONCLUSION

- ✓ **Opzelura addresses major unmet needs of mild-to-moderate atopic dermatitis patients including antipruritic and anti-inflammatory effects**
- ✓ **Expect broad contracted payer coverage**
- ✓ **Strong patient and HCP support system to ensure streamlined access to Opzelura**
- ✓ **Continued future development of ruxolitinib cream**
 - sNDA submission for vitiligo by end of year
 - Pediatric Phase 3 program in atopic dermatitis initiated

