



SOLVE
ON.

OPZELURA™

(ruxolitinib) cream 1.5%

FDA Approval Call for Vitiligo

JULY 19, 2022



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 vitiligo; the Company's plans to commercialize Opzelura; the likelihood that HCPs will prescribe Opzelura; 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, as well as the Company's overall Dermatology program, 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 March 30, 2022. The Company disclaims any intent or obligation to update these forward-looking statements.



HERVÉ HOPPENOT

CHIEF EXECUTIVE OFFICER, INCYTE



**SOLVE
ON.**

First and only FDA approved therapy for repigmentation of nonsegmental vitiligo in the U.S.

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



Clinical trial participant



Robust clinical development program in dermatology

	Indication	Patient Type	Status	Epidemiology (U.S.)
Ruxolitinib Cream	Atopic Dermatitis	Mild/Mod AD (≥12 yrs old)	APPROVED	5.5 million drug-treated patients
		Mild/Mod AD (≥2 to <12 yrs old)	Phase 3 (TRuE-AD3)	2-3 million pediatric patients ¹
	Vitiligo ★	BSA ≤10% (≥12 yrs old)	APPROVED	1.5 million+ diagnosed with vitiligo ² (~80% have BSA ≤ 10%)
	Chronic Hand Eczema	Moderate/Severe	Phase 3 (TRuE-CHE1 / -CHE2) <i>in preparation</i>	4% of population ³
INCB54707	Hidradenitis Suppurativa	Abscess and nodule count ≥ 5	Phase 2	0.1% of population ⁴ (>150,000 have mod/sev HS)
	Vitiligo	BSA ≥ 8% (≥12 yrs old)	Phase 2	1.5 million+ diagnosed with vitiligo ² (~30% have BSA ≥ 8%)
	Prurigo Nodularis	≥20 nodules	Phase 2	> 200,000 patients ⁵

★ Ruxolitinib cream maintenance study ongoing; ruxolitinib cream + phototherapy study ongoing


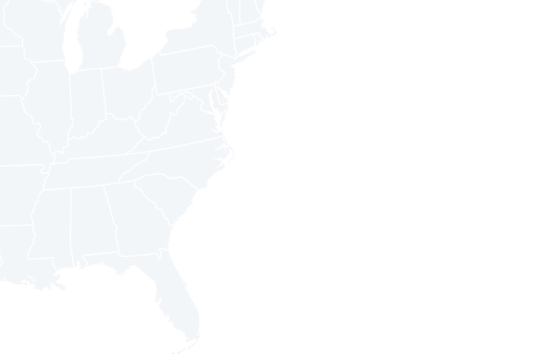



1. DRG; Silverberg JI. *Dermatol Clin.* 2017;35(3):283-289
2. Bergqvist C, Ezzedine K. Vitiligo: A Review. *Dermatology* 2020;236:571-592. doi: 10.1159/000506103
3. Quaade AS, Simonsen AB, Halling AS, Thyssen JP, Johansen JD. Prevalence, incidence, and severity of hand eczema in the general population - A systematic review and meta-analysis. *Contact Dermatitis.* 2021 Jun;84(6):361-374. doi: 10.1111/cod.13804. Epub 2021 Feb 23. PMID: 33548072.
4. Garg A, Kirby JS, Lavian J, Lin G, Strunk A. Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. *JAMA Dermatol.* 2017 Aug 1;153(8):760-764. doi: 10.1001/jamadermatol.2017.0201. PMID: 28492923; PMCID: PMC5710402.
5. <https://www.uptodate.com/contents/prurigo-nodularis>

Establishing a high-growth dermatology franchise



Robust dermatology pipeline - Multiple new launches 2022+

2021	2022	2023	2024+
<p>✓ Opzelura launched in mild to moderate atopic dermatitis¹ in the U.S.</p> 	<p>✓ Opzelura launched in vitiligo¹ in the U.S.</p> 	<p>▪ Opzelura potential approval in vitiligo² in Europe</p> 	<p>Opzelura</p> <ul style="list-style-type: none"> ▪ Chronic hand eczema ▪ Pediatric atopic dermatitis (≥2 to <12 years of age) <p>INCB54707</p> <ul style="list-style-type: none"> ▪ Vitiligo (≥ 8% BSA) ▪ Prurigo nodularis ▪ Hidradenitis suppurativa

Dermatology commercial franchise

- Established U.S. dermatology commercial infrastructure
- Building dermatology presence in Europe (1st launch anticipated in vitiligo)
- Partnerships/collaborations for rest-of-world (ROW)



1. In patients 12 years of age and older
 2. Ruxolitinib cream under review in Europe for vitiligo (12 years of age and older)

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

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

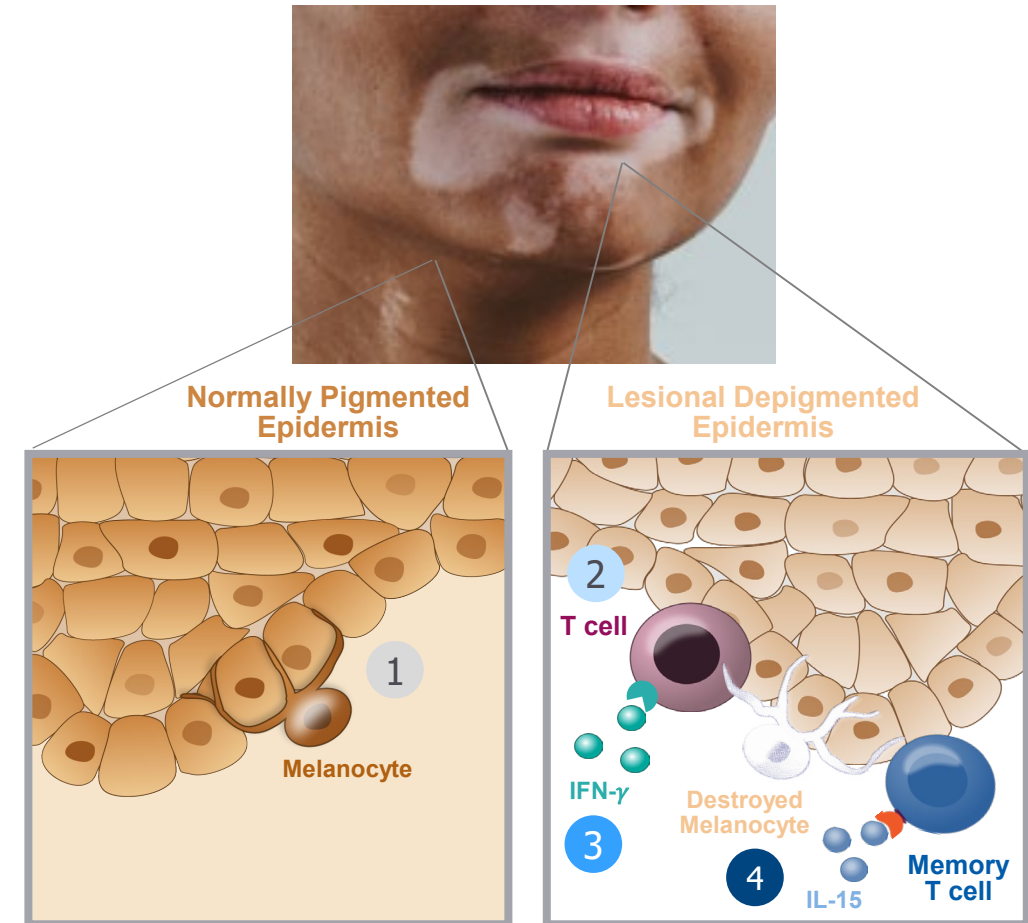


**SOLVE
ON.**

Vitiligo is a chronic autoimmune depigmenting skin disease

Vitiligo Pathogenesis Overview¹⁻⁸

- 1 Melanocyte stress & Innate immune response
- 2 CD8⁺ T cell activation
- 3 IFN- γ inflammatory response
- 4 Progressive melanocyte destruction & depigmentation



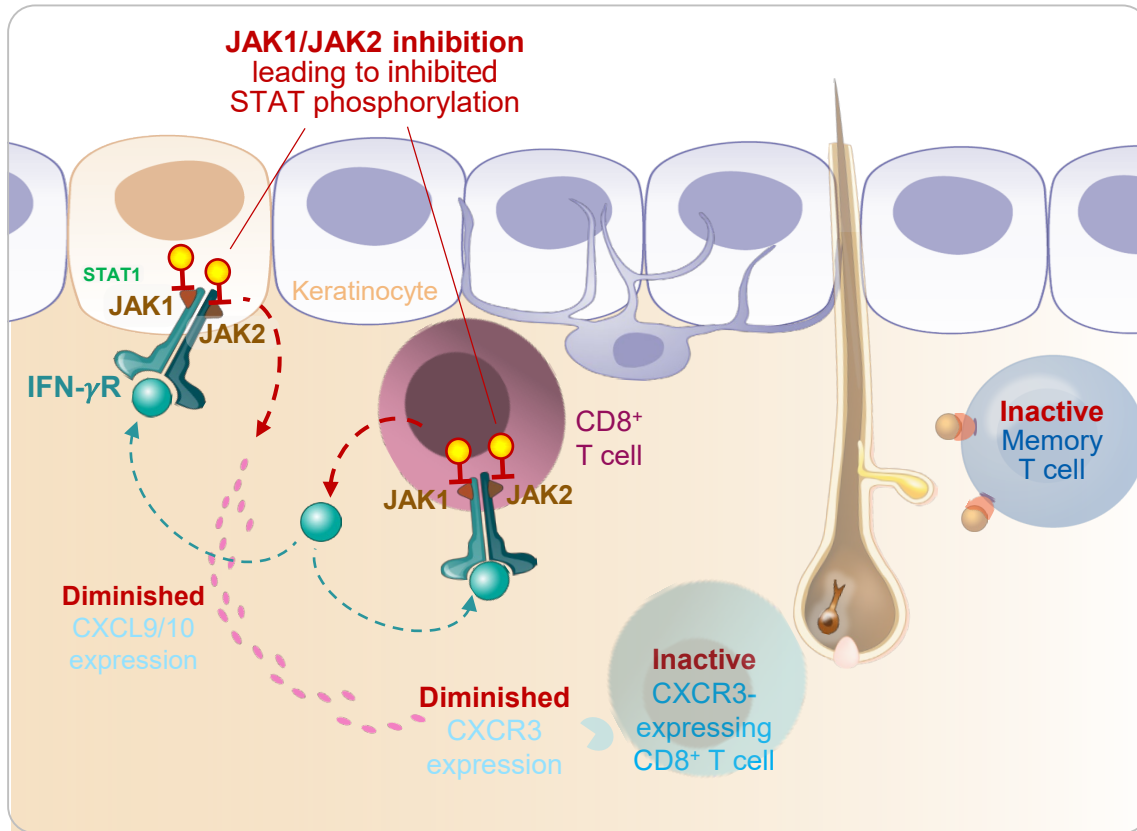
Autoimmune destruction of melanocytes leading to skin depigmentation



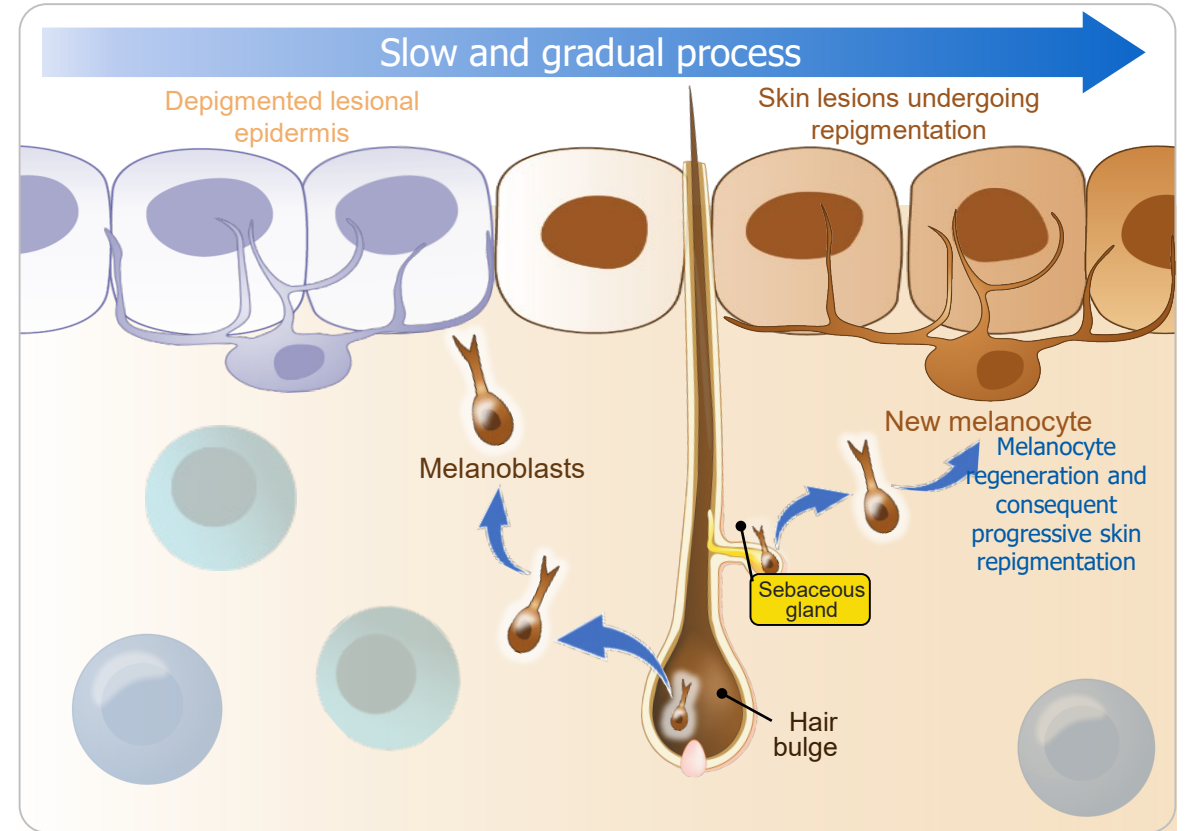
1. Bergqvist C, Ezzedine K. J Dermatol. 2021;48:252-270. 2. Strassner JP, Harris JE. Curr Opin Immunol. 2016;43:81-88. 3. Richmond JM, et al. Curr Opin Immunol. 2013;25:676-682. 4. Frisoli ML, et al. Annu Rev Immunol. 2020;38:621-648. 5. Howell MD, et al. Front Immunol. 2019;10:2342. 6. Rashighi M and Harris JE. Dermatol Clin. 2017;35:257-265. 7. Rosmarin D, et al. Lancet. 2020;396:110-120. 8. Martins C, et al. J Invest Dermatol. 2021. Published online. doi.org/10.1016/j.jid.2021.09.015.

Topical JAK1/JAK2 inhibition may help modulate inflammation-driven destruction of melanocytes and lead to melanocyte regeneration¹⁻⁴

Inhibition of JAK-STAT pathway decreases inflammation-driven autoimmune destruction of melanocytes by disrupting the IFN- γ signaling



Modulating the inflammatory response can create an environment that allows melanocytes to gradually regenerate, resulting in repigmentation over time



U.S. FDA APPROVED LABEL AND CLINICAL DATA



Opzelura U.S. label: Key features from prescribing information

Vitiligo label highlights

- ✓ Approved for **12 years of age and older**
- ✓ Apply to affected areas of up to **10% BSA**
- ✓ Approved for **continuous use** anywhere on body
- ✓ **No limits on duration of use**
- ✓ **52-week efficacy data**
- ✓ **Most common AE was application site acne (6%)**

1 INDICATIONS AND USAGE

1.2 Nonsegmental Vitiligo

OPZELURA is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.3 Recommended Dosage for Nonsegmental Vitiligo

Instruct patients to apply a thin layer of OPZELURA twice daily to affected areas of up to 10% body surface area.

Satisfactory patient response may require treatment with OPZELURA for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.

“Satisfactory patient response may require treatment with OPZELURA for more than 24 weeks.”



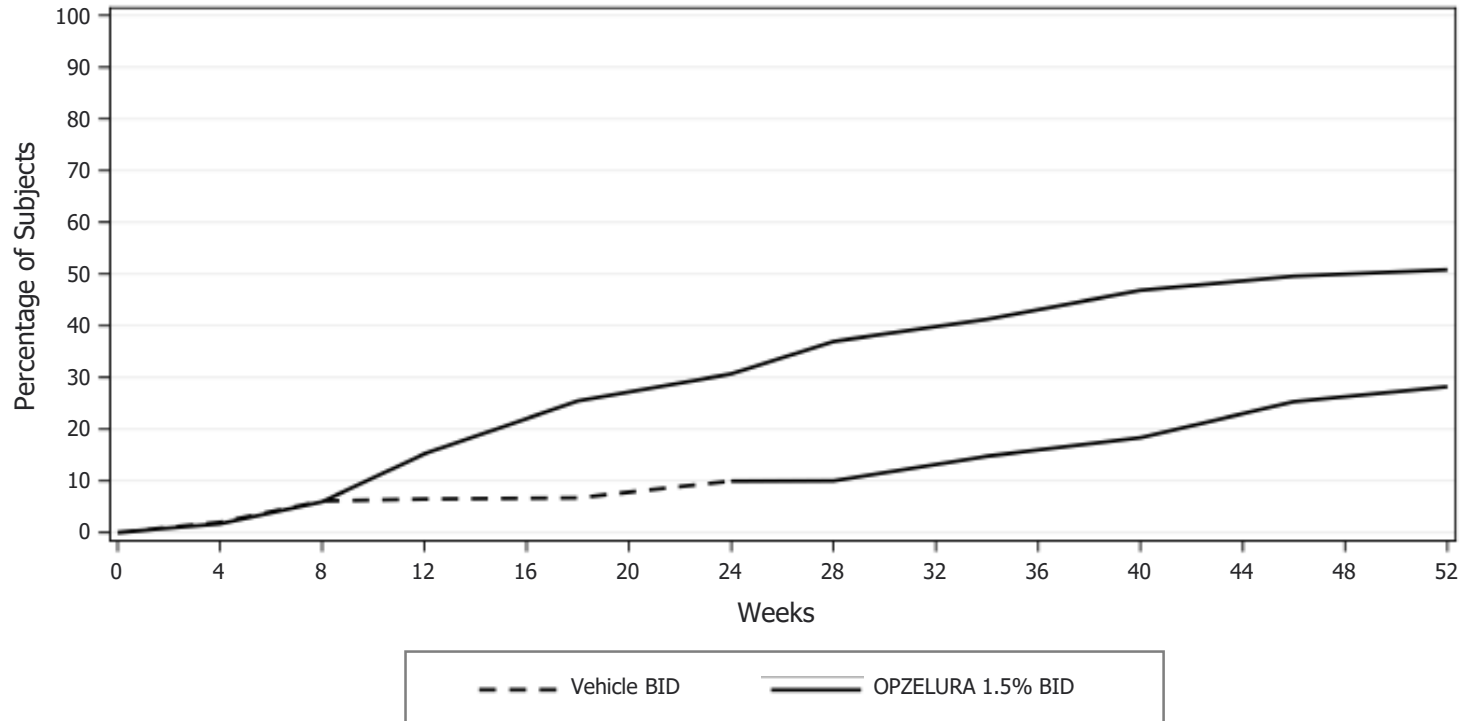
Opzelura U.S. label: Clinically meaningful superiority to vehicle for primary and key secondary endpoints

Week 24	TRuE-V1			TRuE-V2		
	Opzelura™ (ruxolitinib) cream 1.5% N=221	Vehicle N=109	Treatment difference and 95% confidence interval	Opzelura™ (ruxolitinib) cream 1.5% N=229	Vehicle N=115	Treatment difference and 95% confidence interval
≥75% improvement of F-VASI	29.9%	7.5%	22.5% (14.2%, 30.8%)	29.9%	12.9%	16.9% (7.8%, 26.0%)
≥90% improvement of F-VASI	15.5%	2.2%	13.3% (7.5%, 19.1%)	15.4%	1.9%	13.5% (7.7%, 19.3%)



Opzelura U.S. label: 52 week efficacy data

Percentage of Subjects with Nonsegmental Vitiligo Achieving F-VASI75 During the 52-Week Treatment Period



Takeaways

- Higher proportion of patients responded with longer duration of treatment
- Efficacy at Week 52 in crossover patients was consistent with Week 24 data in patients who applied Opzelura from Day 1



Opzelura U.S. label: Safety

Adverse Reactions Occurring in $\geq 1\%$ of Subjects Treated with OPZELURA for Nonsegmental Vitiligo through Week 24 in TRuE-V1 and TRuE-V2

Adverse Reaction	OPZELURA (N=449) n (%)	Vehicle (N=224) n (%)
<i>Subjects with any TEAE*</i>	214 (48)	79 (35)
<i>Application site acne</i>	26 (6)	2 (1)
<i>Application site pruritus</i>	23 (5)	6 (3)
<i>Nasopharyngitis</i>	19 (4)	5 (2)
<i>Headache</i>	17 (4)	6 (3)
<i>Urinary tract infection</i>	7 (2)	1 (<1)
<i>Application site erythema</i>	7 (2)	1 (<1)
<i>Pyrexia</i>	6 (1)	0

Takeaways

- No new safety signals
- Discontinuation rate due to AE's was 0.4% for both Opzelura and vehicle arms¹
- Low frequency of serious AEs (1.8% Opzelura, 0.4%, vehicle) with none considered related to treatment¹
- JAK class updates to Warnings and Precautions Section

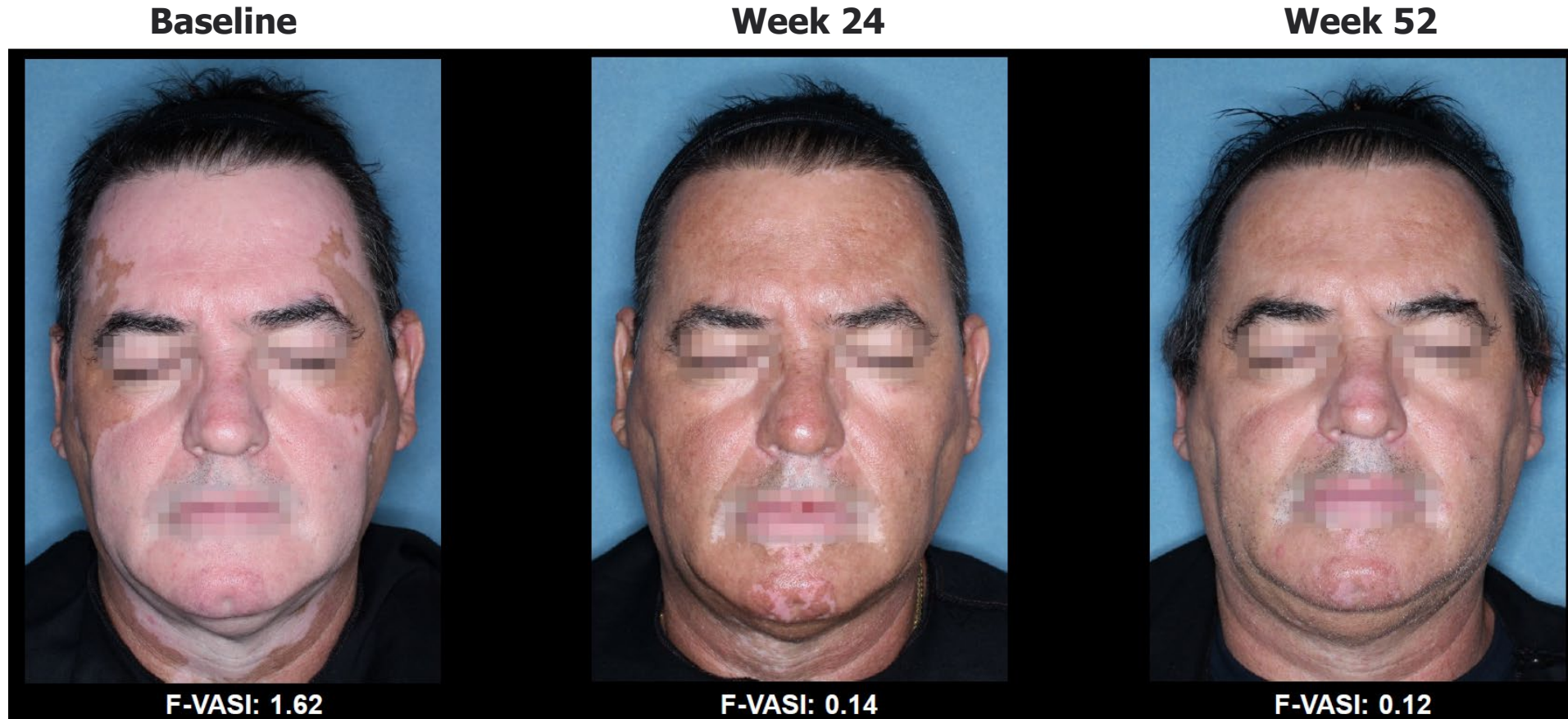


*TEAE = treatment emergent adverse events

Opzelura [package insert] Wilmington, DE. Incyte Corporation: 2022

1. Rosmarin D, et al. Efficacy and Safety of Ruxolitinib Cream for the Treatment of Vitiligo: Week 24 Pooled Analysis of the TRuE-V Phase 3 studies. AAD 2022. Boston, MA. March 2022

TRuE-V: F-VASI response of patient on Opzelura 1.5% BID

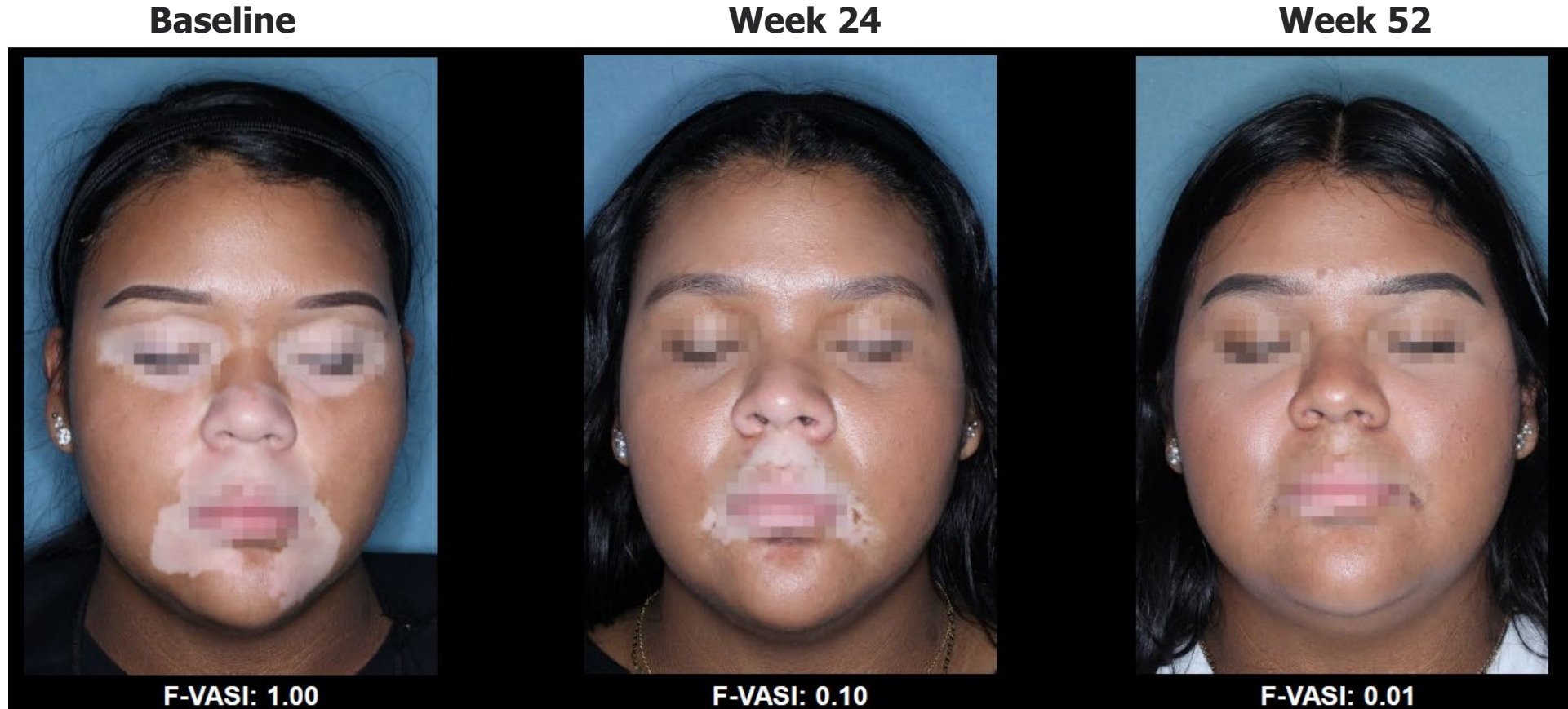


56 year-old male patient; disease duration, 21.6 years



Clinical trial participant; individual results may vary.
F-VASI= facial Vitiligo Area Scoring Index.
Rosmarin D, et al. AAD 2022. Late-breaking oral presentation.

TRuE-V: F-VASI response of patient on Opzelura 1.5% BID



14 year-old female patient; disease duration, 10.4 years



Clinical trial participant; individual results may vary.
F-VASI= facial Vitiligo Area Scoring Index.
Rosmarin D, et al. AAD 2022. Late-breaking oral presentation.

TRuE-V: T-VASI response of patient on Opzelura 1.5% BID

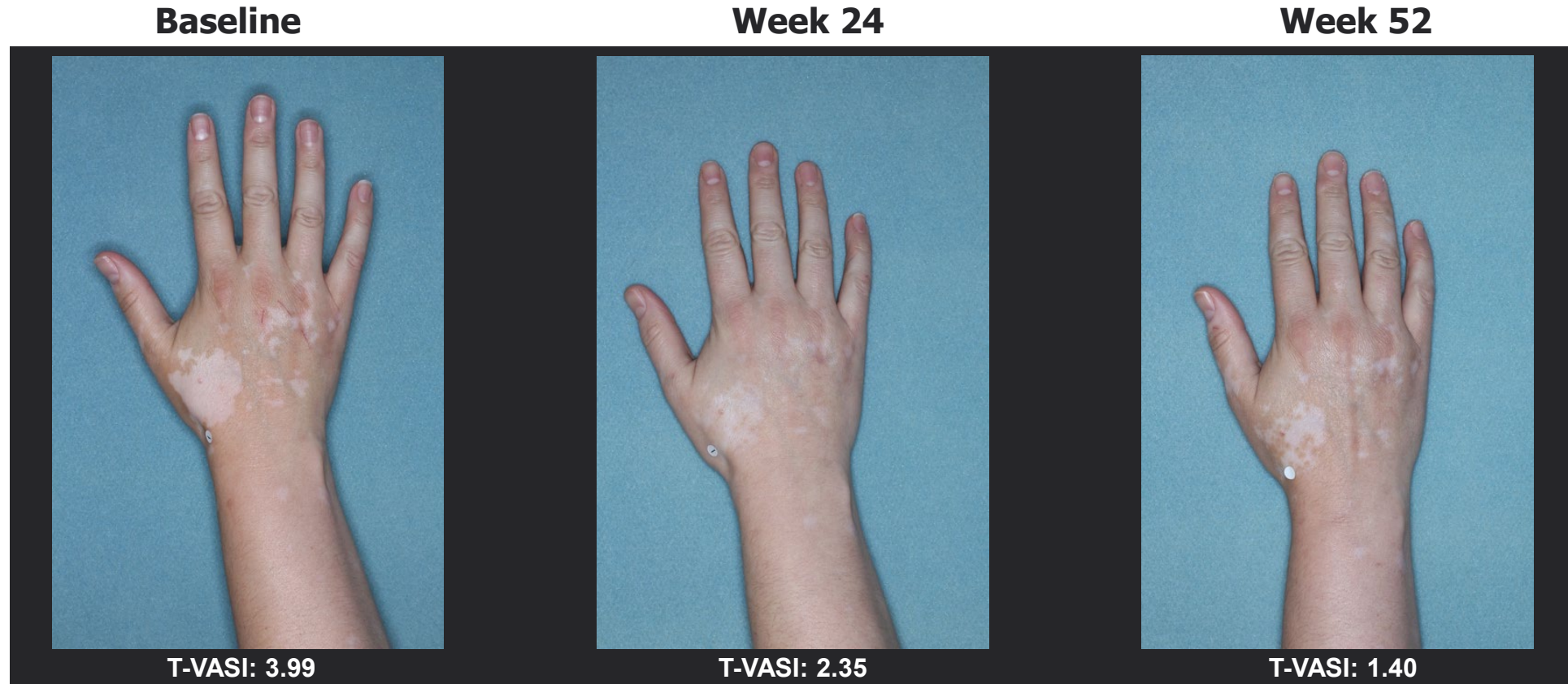


66 year-old female patient; disease duration, 54.4 years



Clinical trial participant; individual results may vary.
T-VASI = total body Vitiligo Area Scoring Index. T-VASI scores indicated on the figure reflect the whole body of the patients and not only the body parts shown on the pictures.
Rosmarin D, et al. AAD 2022. Late-breaking oral presentation.

TRuE-V: T-VASI response of patient on Opzelura 1.5% BID



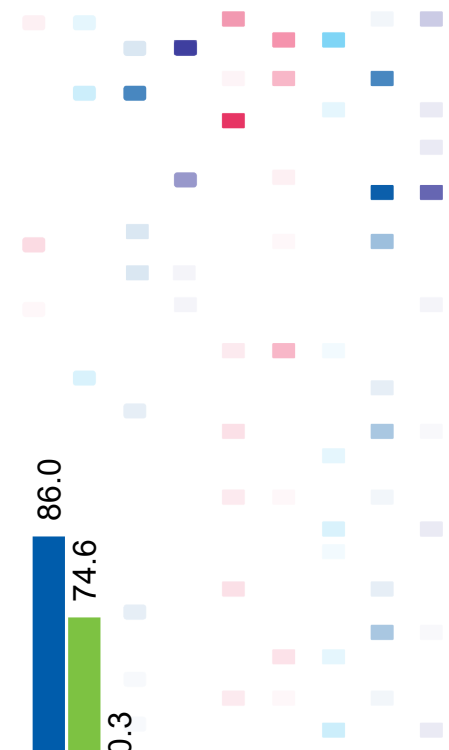
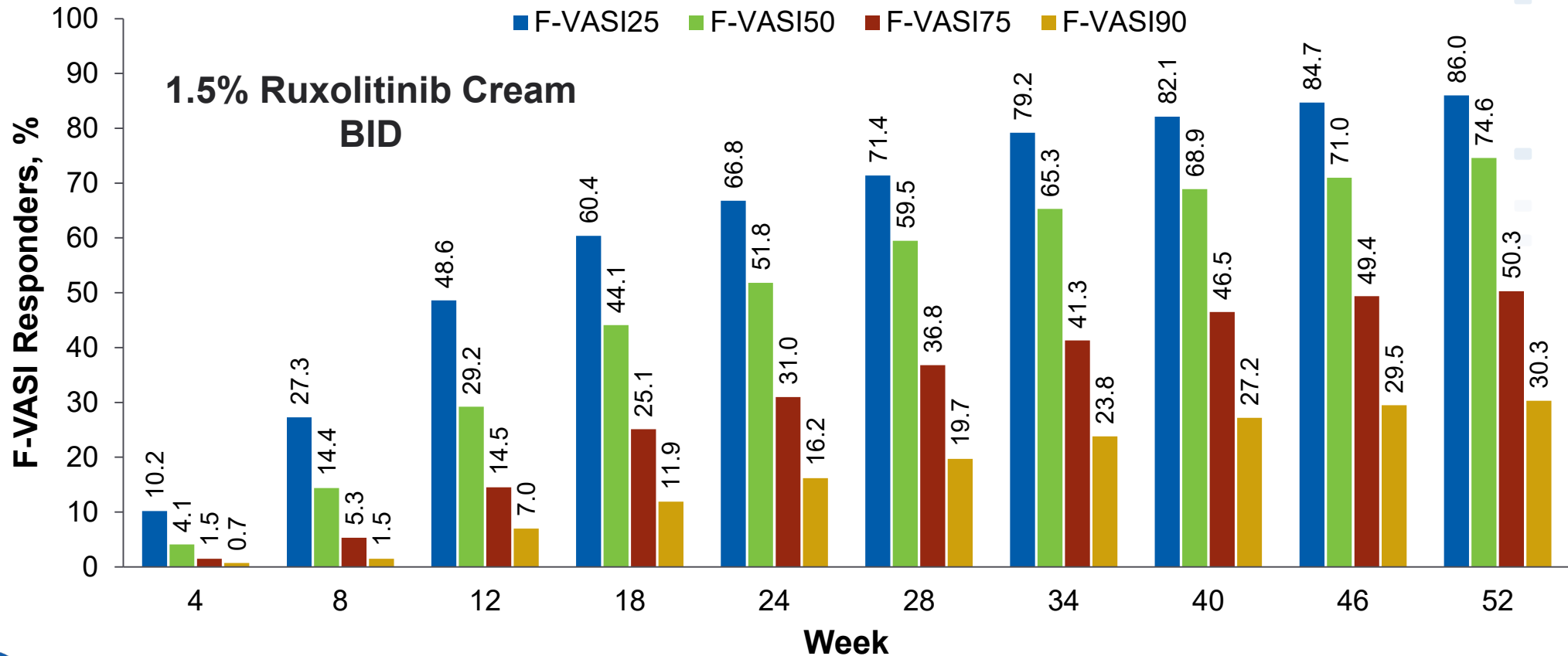
37 year old female patient; disease duration, 8.0 years



Clinical trial participant; individual results may vary.
T-VASI = total body Vitiligo Area Scoring Index. T-VASI scores indicated on the figure reflect the whole body of the patients and not only the body parts shown on the pictures.
Rosmarin D, et al. AAD 2022. Late-breaking oral presentation.

TRuE-V: F-VASI Response By Study Visit

- Almost 50% of patients achieve F-VASI25 by Week 12; 86% by Week 52
- 30% of patients achieve F-VASI90 by Week 52



SEEMAL R. DESAI, M.D.

**CLINICAL ASSISTANT PROFESSOR
DEPARTMENT OF DERMATOLOGY
UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
FOUNDER & MEDICAL DIRECTOR
INNOVATIVE DERMATOLOGY, PA
DALLAS, TEXAS**

VITILIGO

- Prevalence in U.S. and Europe is between 1-3%
- Each sex equally affected
- Often seen in pediatric, adolescent, young and old adults
- Over 1/2 of the patients affected, show signs before age 20

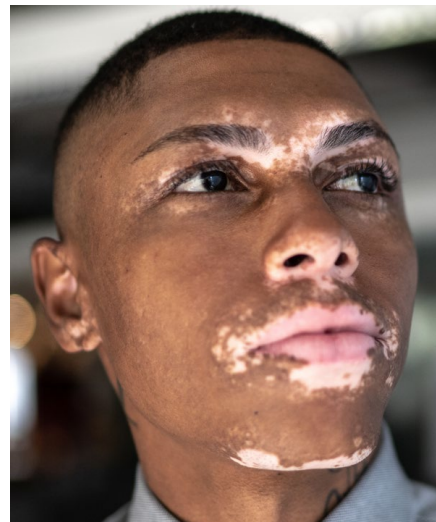




Image on left reproduced with permission from Science Photo Library (www.sciencephoto.com [sciencephoto.com]). Copyright © Mid Essex Hospital Services NHS Trust / Science Photo Library.
Image on right reproduced with permission from Science Photo Library (www.sciencephoto.com [sciencephoto.com]). Copyright © Dr Harout Tanielian / Science Photo Library.



VITILIGO IMPACT ON PATIENTS

- Vitiligo has been associated with variety of psychological impacts and burden
- Stigmatizing, challenging condition
- Tough to treat
- Many patients have given up hope

MANAGEMENT OF VITILIGO

- Topicals including steroids, vitamin D analogues, calcineurin inhibitors
- Depigmentation
- Systemic therapies
- Phototherapy
- Surgical treatment
- Psychological treatment

- **IF TREATMENTS FAIL → ANALYZE PATIENTS DESIRES**

OPZELURA IN VITILIGO

- Repigmentation in typically difficult to treat areas, including hands
- Precision of color match of repigmentation
- Potential for fairly robust results early in treatment process
- Non-steroidal option (use on face and other sensitive areas)
- Prescribing flexibility (duration, in combination with phototherapy, etc)

OPZELURA'S PLACE IN TREATMENT

- First-line option for majority of vitiligo patients seeking treatment
- Use in areas most likely to respond (head/neck)
- Use in areas that are most challenging to treat (hands/feet)
- Important to set expectations for patients

- **PATIENTS HAVE BEEN WAITING A LONG TIME FOR THIS!**

TODD EDWARDS

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



**SOLVE
ON.**

PATIENT VIDEO

BERARDO



**SOLVE
ON.**

1.5 million+ diagnosed with vitiligo; no approved therapies for repigmentation

SIGNIFICANT UNMET NEED

Diagnosed vitiligo patients in the US



150-200k patients are actively seeking treatment

IMPACT ON PATIENTS

Patients with **vitiligo** were

5x more likely

to have **depression** than peers

Among patients with **vitiligo**

75%

worried about their disease **getting worse**

LIMITED AVAILABLE THERAPIES

NO approved therapies for repigmentation prior to Opzelura

Topical steroids

Limited efficacy, skin atrophy

Topical calcineurin inhibitors

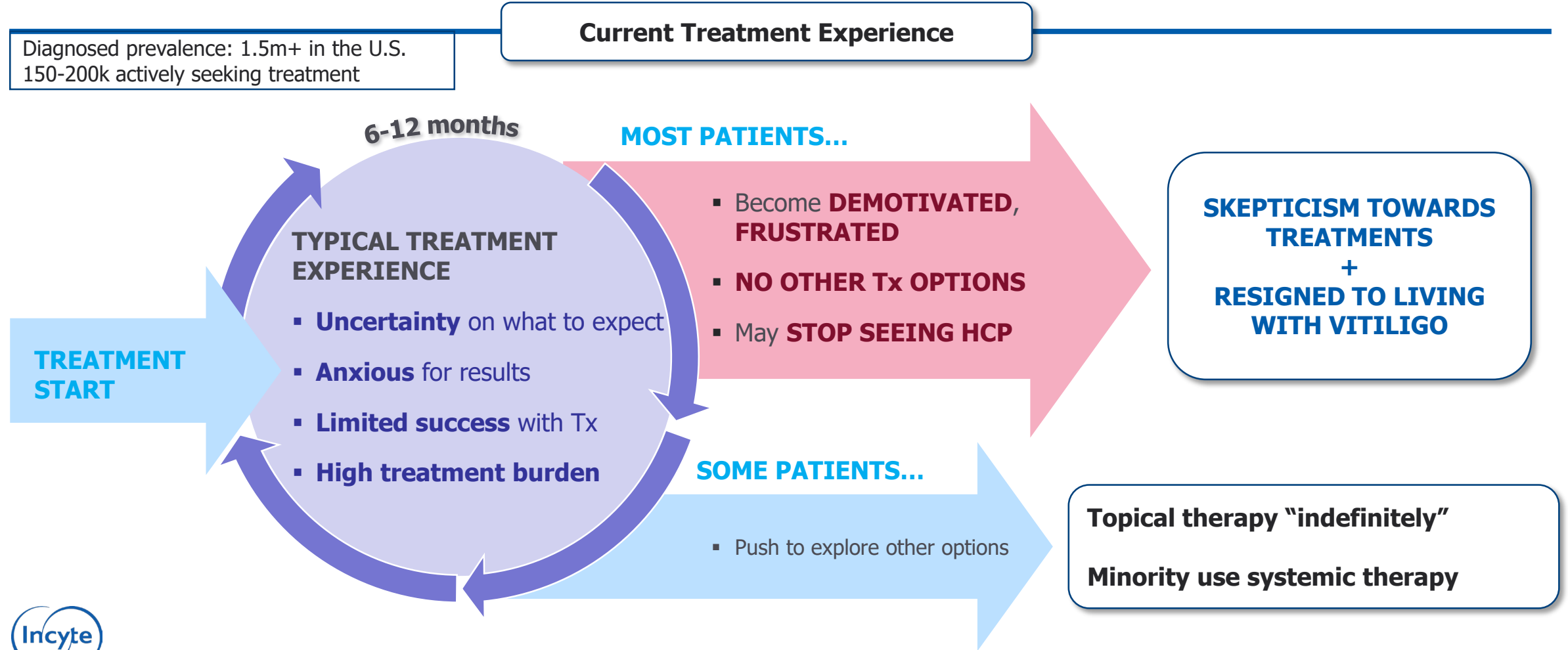
Burning sensation

Narrow-band UVB phototherapy

3x/wk > 1yr, patient burden



Typical vitiligo patient treatment experience has resulted in disappointment, leaving many resigned to living with the disease



Opzelura is uniquely positioned to change the treatment landscape for physicians and the treatment experience for patients

Repigmentation improvement in the majority of patients

Approved for continuous use including on sensitive areas

Well-tolerated AE profile

Light, non-greasy cream formulation



An innovative, effective therapy for dermatologists to offer to their vitiligo patients



Product

- ✓ First and only approved therapy for repigmentation
- ✓ Largest positive randomized clinical trial in vitiligo
- ✓ Compelling efficacy

Prescriber

- ✓ Significant prescriber overlap
- ✓ Positive experiences with Opzelura

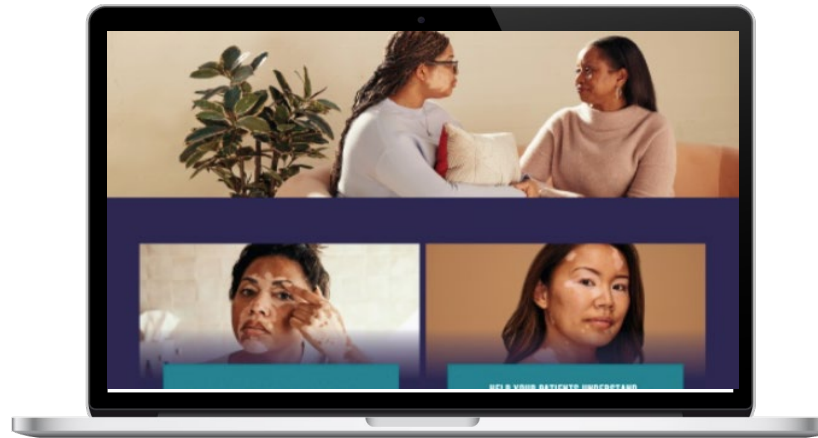
Activities

- ✓ Comprehensive and targeted multi-channel marketing campaign

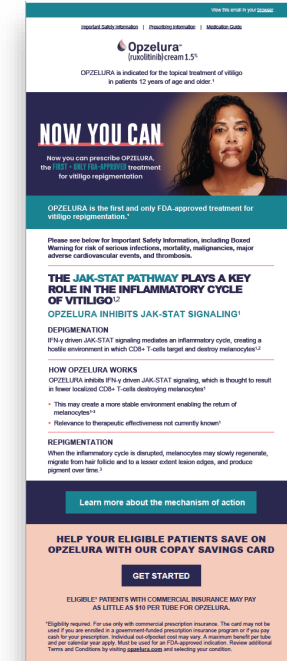
Engage patients and increase awareness



Active multimedia campaign to drive awareness



Patient website and educational resources



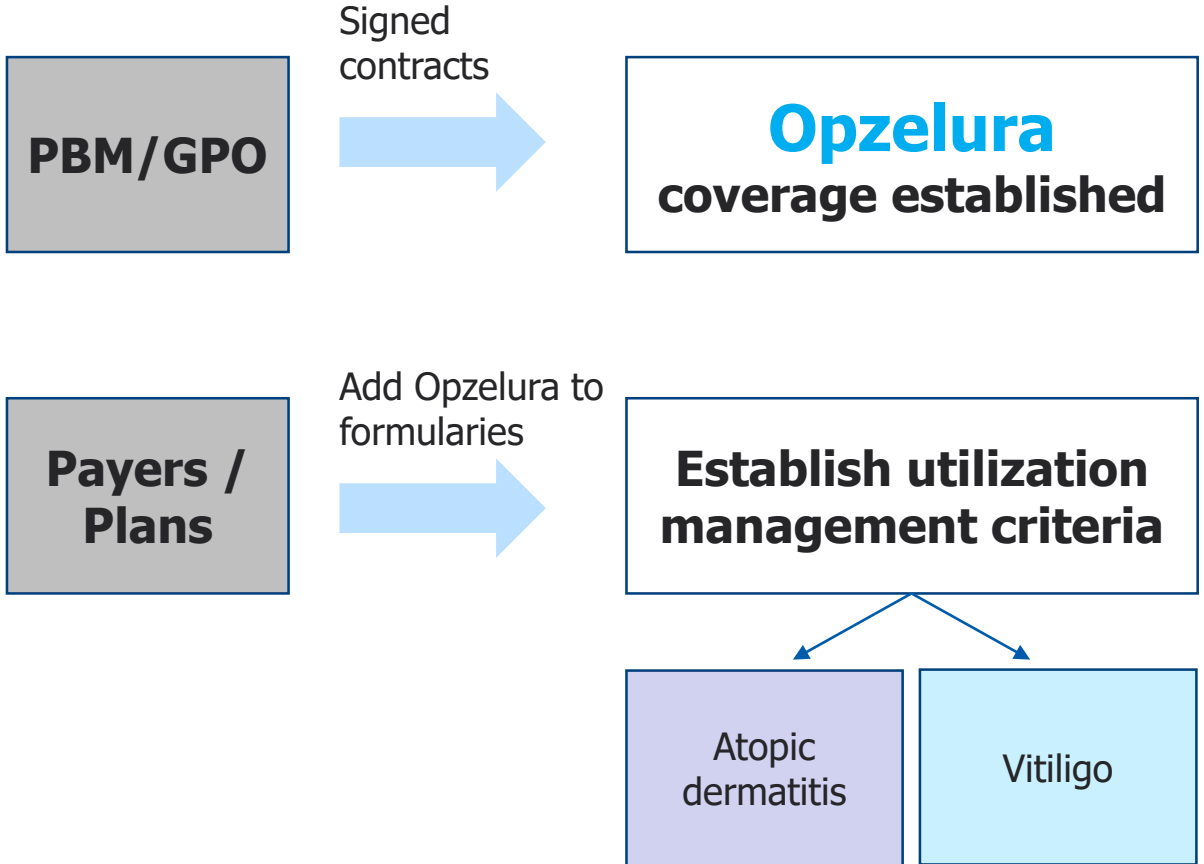
Co-pay mitigation and other support programs



Proactive engagement of payers for Opzelura in vitiligo



- **Opzelura:**
 - ✓ **First approved drug for repigmentation**
 - ✓ **Addresses a large unmet need**
- **Work with payers to ensure patients have access to Opzelura**



HERVÉ HOPPENOT

CHIEF EXECUTIVE OFFICER, INCYTE



**SOLVE
ON.**

Conclusion

Market Opportunity

- Vitiligo diagnosed prevalence: 1.5 million+ in the U.S. and 2 million+ in Europe
- First ever approved therapy for repigmentation in vitiligo

Launch Readiness

- Dermatology commercial team fully in place and launch ready
- Significant prescriber overlap between AD and vitiligo
- Strong patient/physician support to ensure streamlined access to Opzelura
- Leveraging existing PBM contracts for Opzelura

Extension of Franchise

- CHMP opinion for Opzelura in vitiligo in Europe by end of year
- Robust dermatology development program planned with Opzelura and INCB54707

