Revolutionizing the Treatment of Vitiligo

Investor/Analyst event at AAD 2023

MARCH 18, 2023

Forward-looking statements

Except for the historical information set forth herein, the matters set forth in this presentation, including without limitation statements regarding Incyte's expectations for the future of vitiligo treatment; Incyte's expectations with respect to the potential of Opzelura, povorcitinib and auremolimab to provide successful treatments for patients with vitiligo; Incyte's TRuE-V program and other clinical trials in vitiligo; and Incyte's inflammation and autoimmunity programs generally, contain predictions, estimates and other forward-looking statements.

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; the effects of the COVID-19 pandemic and measures to address the pandemic on our clinical trials, supply chain and other third-party providers, sales and marketing efforts, and business, development, and discovery operations, as well as on regulatory agencies such as the FDA; 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; determinations made by the FDA and regulatory agencies outside of the United States; our dependence on relationships with and changes in the plans and expenditures of our collaboration partners; the efficacy or safety of our products and the products of our collaboration partners; the acceptance of our products and the products of our collaboration partners in the marketplace; market competition; unexpected variations in the demand for our products and the products of our collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for our products and the products of our collaboration partners; sales, marketing, manufacturing, and distribution requirements, including our and our collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our annual report for the year ending December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

AGENDA & WELCOME

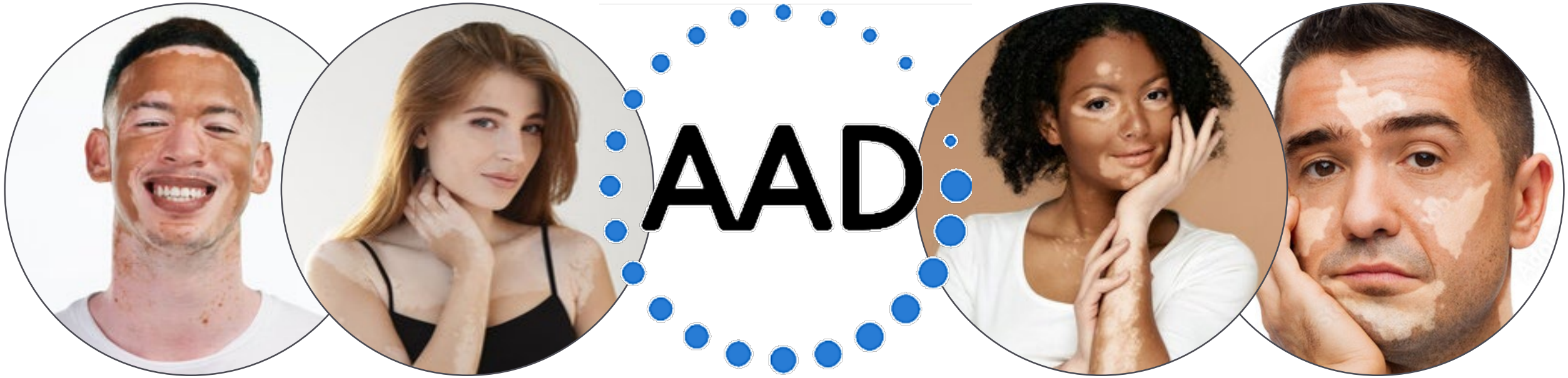
JIM LEE, MD, PhD

GVP, HEAD OF INFLAMMATION AND AUTOIMMUNITY

Incyte | SOLVE ON.

Incyte: Revolutionizing vitiligo therapy….

…One patient at a time



Incyte: Committed to making vitiligo history

*A treatment to **fit every patient*** *Across the **vitiligo spectrum***

1.5M patients diagnosed

Opzelura™

≤10% BSA

80% of patients

Povorcitinib

≥8% BSA

30% of patients

Auremolimab

Depletion of T_{RM}

Durability of response

Incyte

Bergqvist C, Ezzedine K. Vitiligo: A Review. Dermatology 2020;236:571-592. doi: 10.1159/000506103;

Agenda

5:30 – 6:30 pm

Jim Lee, MD, PhD — **Ruxolitinib cream in vitiligo: TRuE-V LTE (52-104 weeks)**

- Cohort A (≥F-VASI90): Relapse and maintenance in patients re-randomized to ruxolitinib cream or vehicle
- Cohort B (<F-VASI90): F-VASI and T-VASI response shift with 104 weeks of ruxolitinib cream treatment

Amit Pandya, MD — **Povorcitinib in vitiligo: Phase 2b results**

- T-VASI and F-VASI at 24 weeks

Vitiligo: Treatment and Novel Therapeutics in Development

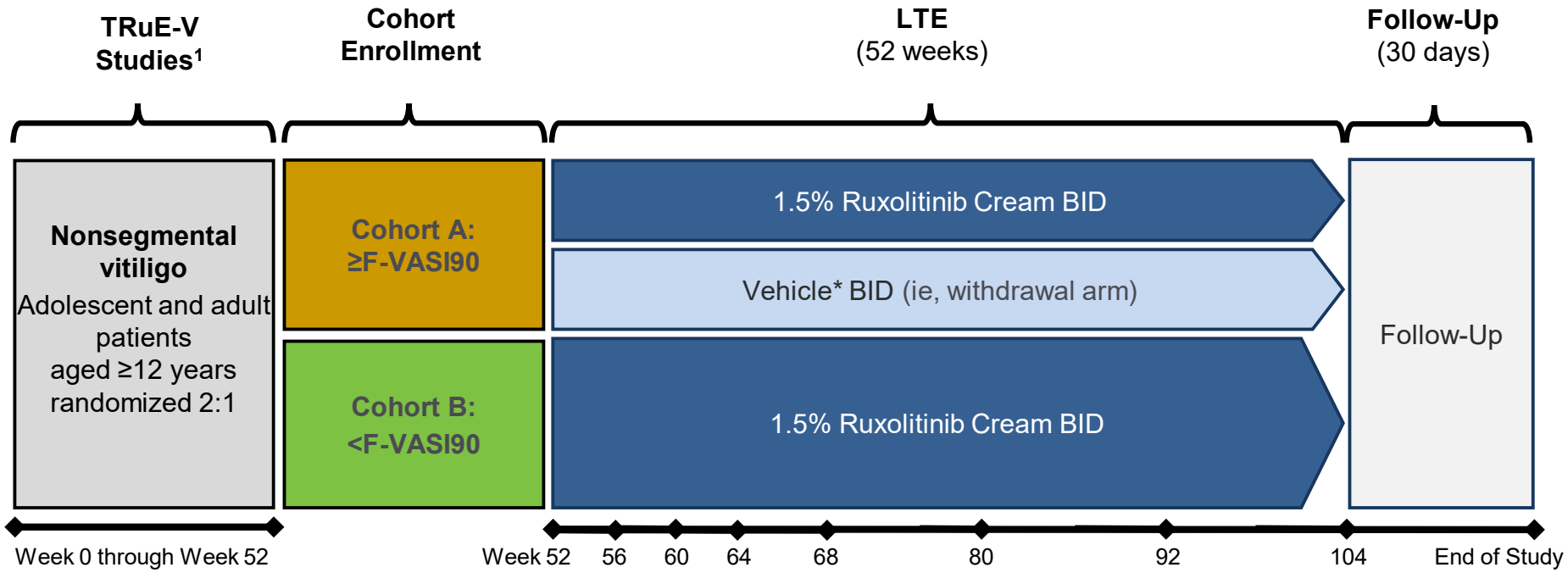
6:30 – 7:00 pm

Q & A (Steven Stein, Jim Lee, Amit Pandya)

RUXOLITINIB CREAM
TRuE-V1/V2 long-term extension
104 weeks

Incyte | SOLVE ON.

TRuE-V long-term extension (LTE): Study design

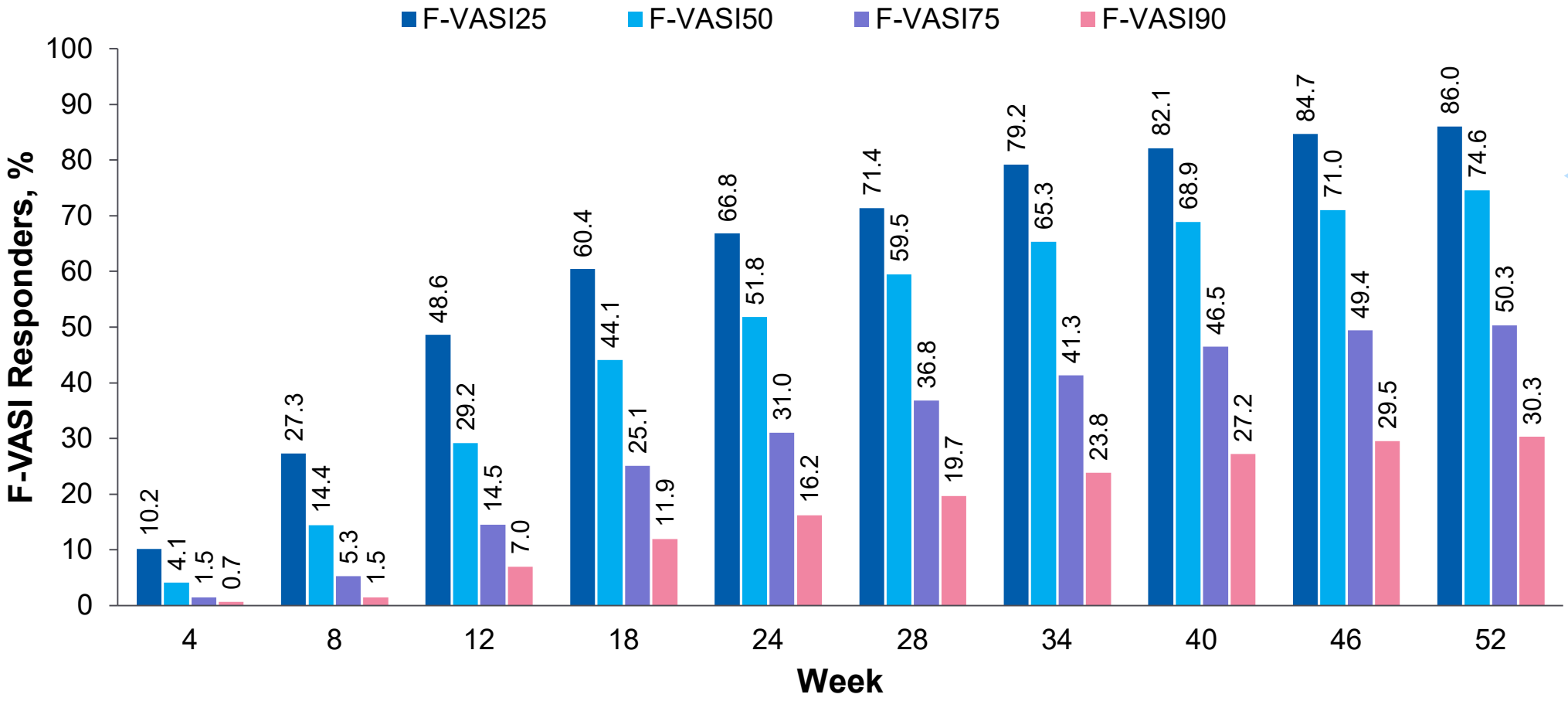


Objective is to evaluate:

- **Cohort A:** Time to relapse (<F-VASI75) in patients randomized to vehicle
- **Cohort A:** Duration of response in patients randomized to vehicle or rux cream
- **Cohort B:** Change (or stability) in F-VASI/T-VASI

BID, twice daily.
* Patients randomized to vehicle who relapsed (ie, <F-VASI75) could apply 1.5% ruxolitinib cream BID rescue treatment for the remainder of the LTE period.
1. Rosmarin D, et al. N Engl J Med. 2022;387:1445-1455.

TRuE-V: F-VASI Response By Study Visit

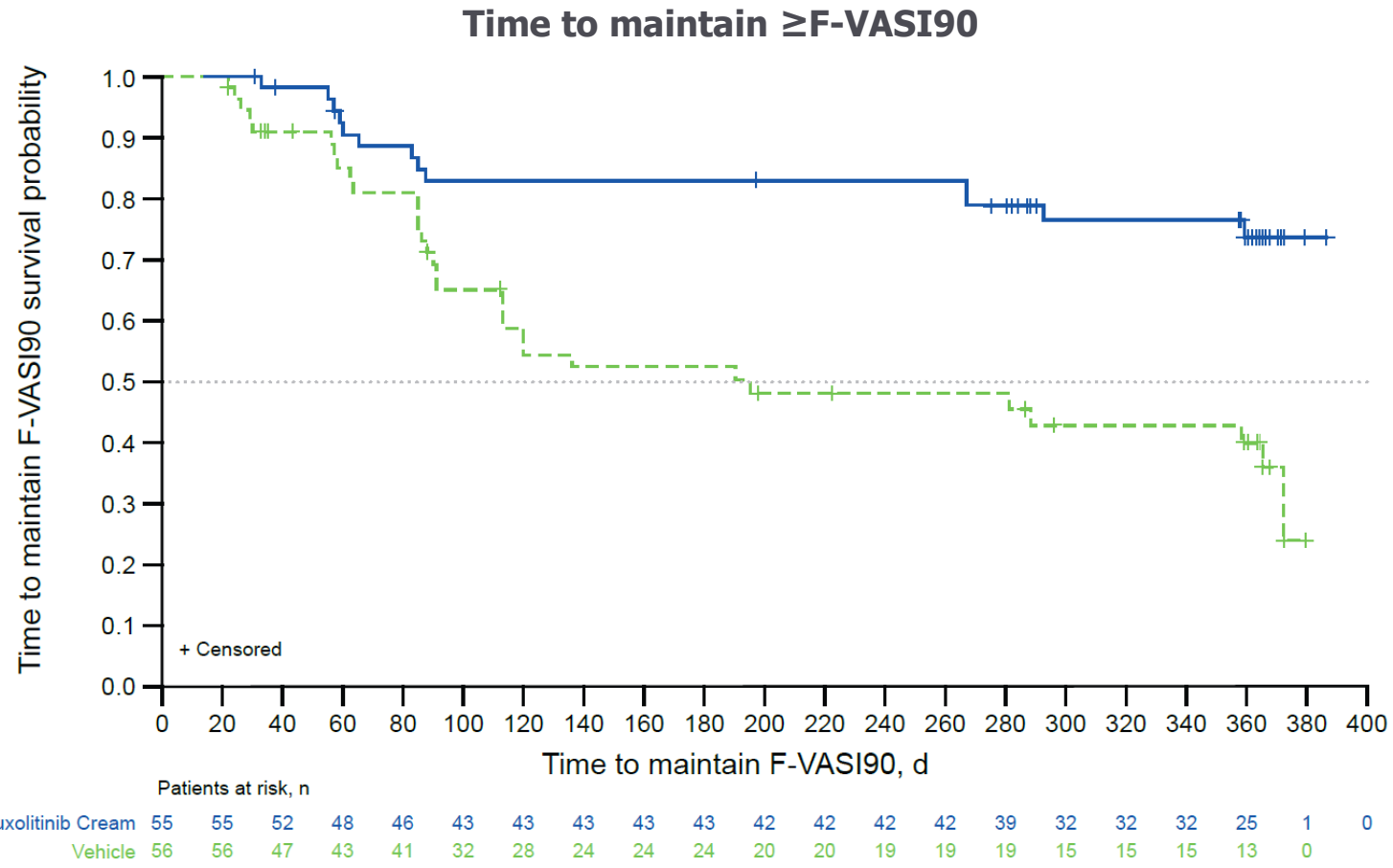


Responses at Wk 52

- F-VASI**25**: 86%
- F-VASI**50**: 75%
- F-VASI**75**: 50%
- F-VASI**90**: 30%

Data on File

Cohort A: Maintenance of ≥F-VASI90 response



Maintenance of ≥F-VASI90
(Week 52 to Week 104)

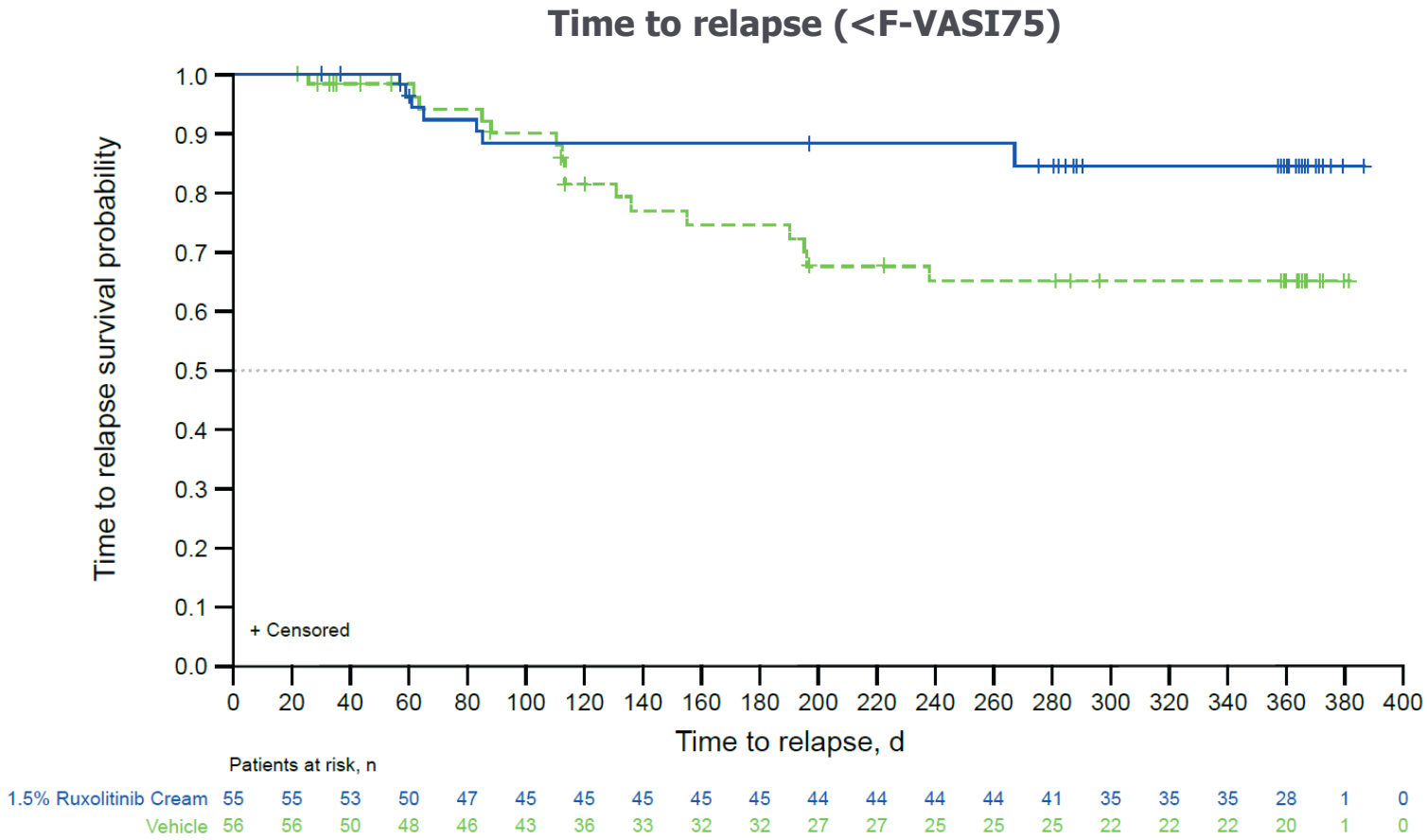
Majority of patients continuing on rux cream maintained ≥F-VASI90
- mDOR (≥F-VASI90) was NE

21.4% in withdrawal arm maintained ≥F-VASI90 for 1 year
- mDOR (≥F-VASI90) was 195 days

Discontinuation rates prior to 1 year
- 17.9% on vehicle
- 10.9% on ruxolitinib cream

NE, not estimable

Cohort A: Time to relapse (<F-VASI75) in patients



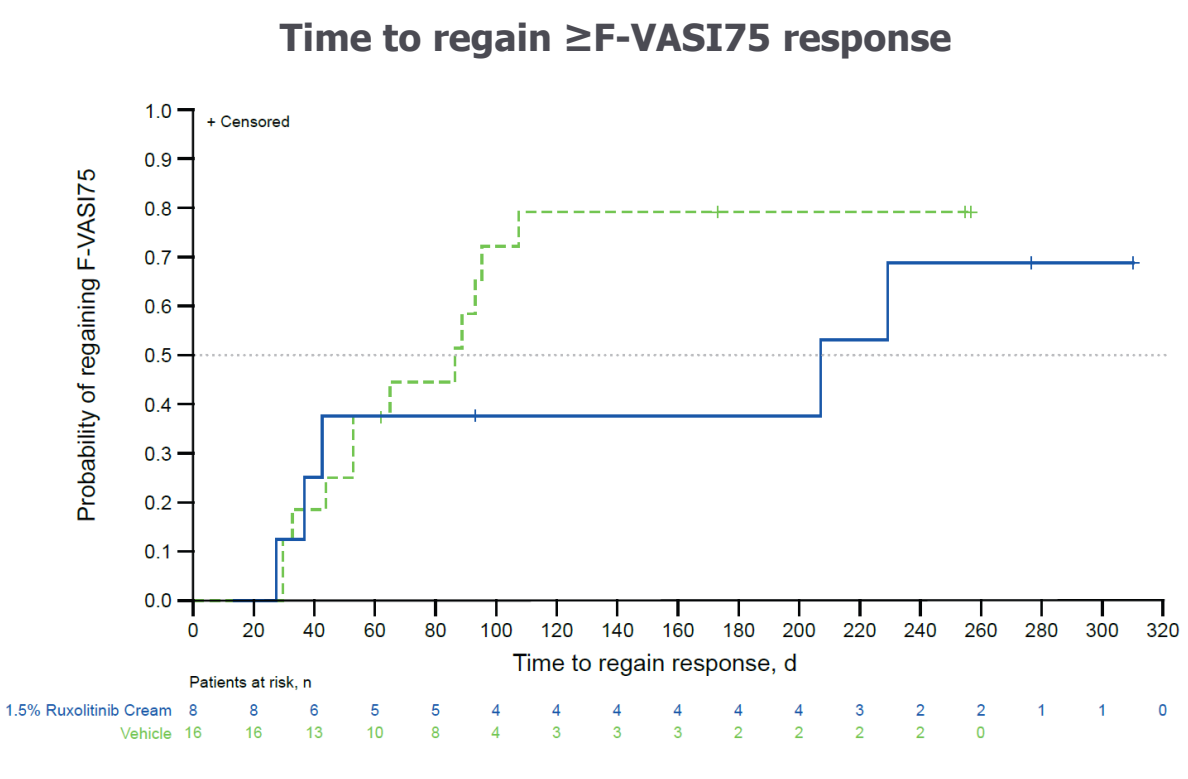
Time to relapse
(Week 52 to Week 104)

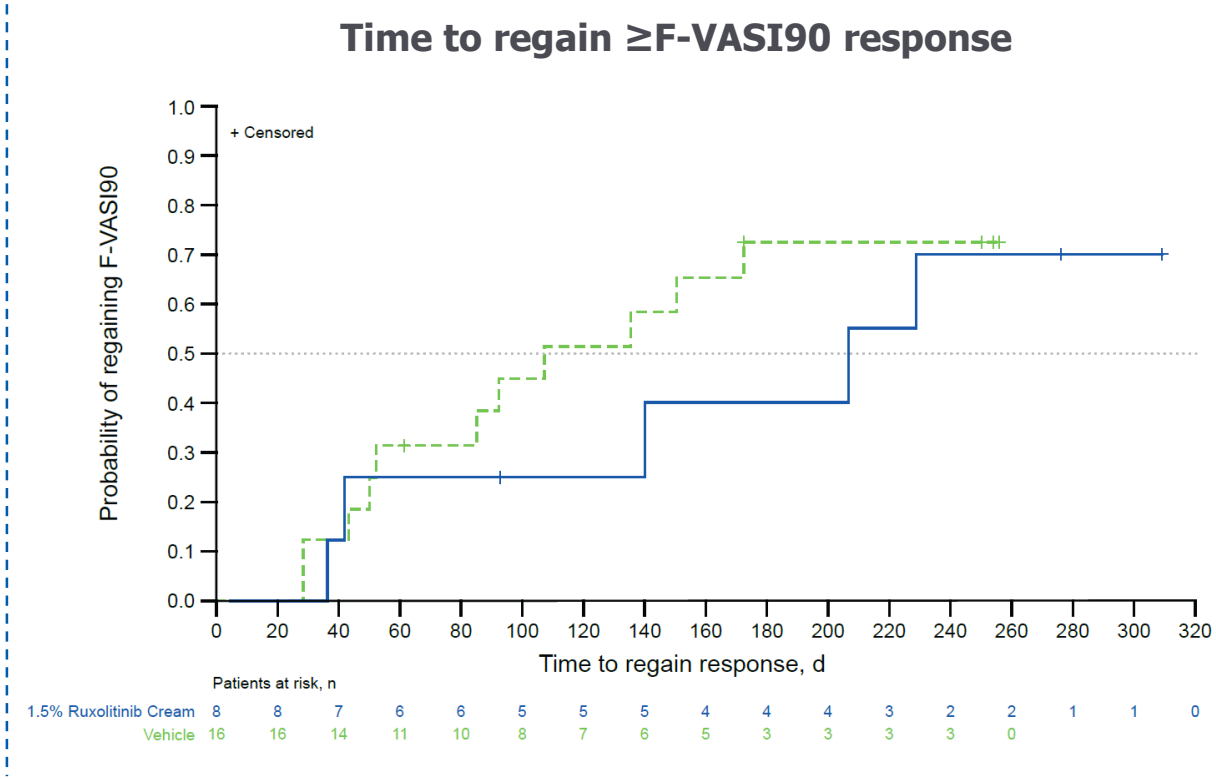
29% of patients who were withdrawn from ruxolitinib cream relapsed

- Half of relapses occurred within 4 months

23.2% of patients in the withdrawal arm discontinued treatment prior to 1 year

Cohort A: Patients who relapse quickly regain ≥F-VASI75 and ≥F-VASI90





Of patients who relapsed during treatment withdrawal and re-initiated ruxolitinib cream:

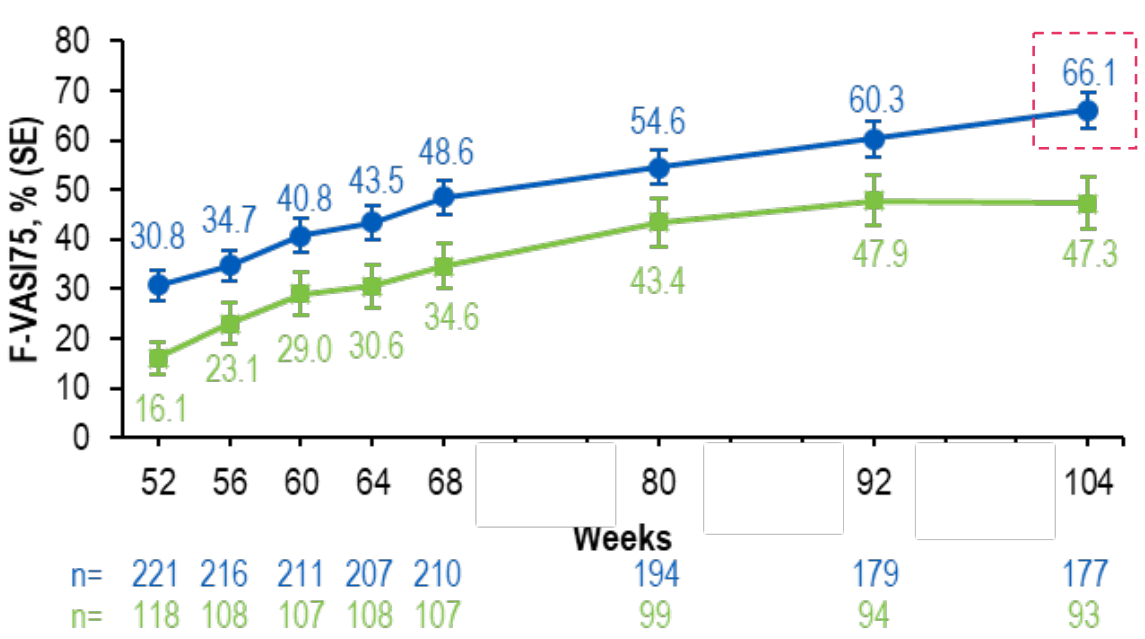
- **75.0%** regained ≥F-VASI75 response (median of 12 weeks)
- **68.8%** regained ≥F-VASI90 response (median of 15 weeks)

12/16 patients regained ≥F-VASI75; 11/16 patients regained ≥F-VASI90

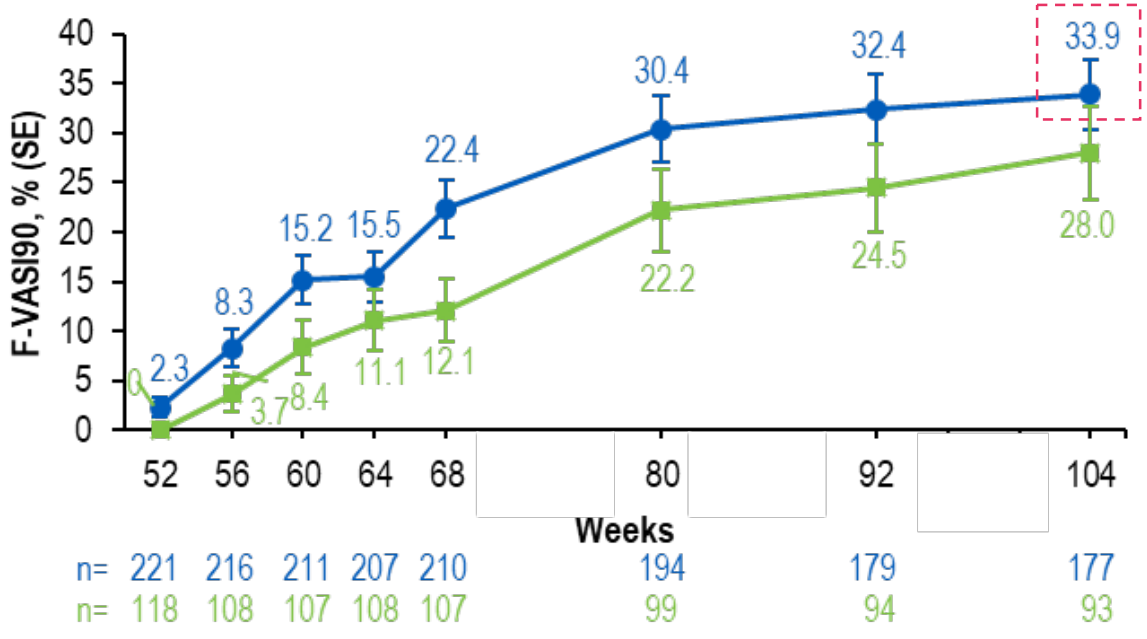
Cohort B: Week 52-104 responses in patients who had <F-VASI90 at Wk 52

Continued treatment with ruxolitinib cream led to increased responses; ~30% achieved F-VASI90 by Wk 104

*66% of patients applying ruxolitinib cream since Day 1 achieved **F-VASI75** at Week 104, up from 31% at Week 52*



*34% of patients applying ruxolitinib cream since Day 1 achieved **F-VASI90** at Week 104, up from 2% at Week 52*



1.5% ruxolitinib cream since Day 1 (n=222)

Vehicle to Wk 24; 1.5% ruxolitinib cream to Wk 104 (n=118)

* Five patients were incorrectly assigned to Cohort B at LTE baseline.

Treatment with ruxolitinib cream was well-tolerated through 104 weeks

Cohort A

Characteristic, n (%)	Vehicle (n=58)	Ruxolitinib Cream* (n=81)
Patients with TEAE	21 (36.2)	35 (43.2)
Most common TEAEs†		
COVID-19	6 (10.3)	10 (12.3)
Upper respiratory tract infection	0	4 (4.9)
Application site dermatitis	0	3 (3.7)
Headache	2 (3.4)	2 (2.5)
Nasopharyngitis	2 (3.4)	2 (2.5)
Toothache	2 (3.4)	1 (1.2)
Bronchitis	2 (3.4)	0
Cough	2 (3.4)	0
Muscle strain	2 (3.4)	0
Skin papilloma	2 (3.4)	0
Patients with treatment-related TEAE	3 (5.2)	3 (3.7)
Patients with application site reactions	2 (3.4)	5 (6.2)
Patients with serious TEAE‡	0	1 (1.2)‡
Patients with TEAE leading to discontinuation	0	0
Patients with TEAE leading to dose reduction	0	1 (1.2)

- There were no cases of application site acne or application site pruritus among patients who applied ruxolitinib cream in Cohort A

Cohort A: TEAE, treatment-emergent adverse event.
* Including 23 patients restarted active treatment upon relapse
† Occurring in ≥3% of patients in any treatment group.
‡ Uterine leiomyoma was considered by the investigators to be unrelated to treatment.

Cohort B

Characteristic, n (%)	Ruxolitinib cream from Day 1 (n=224)	Vehicle to ruxolitinib cream (n=118)	Overall (N=342)
Patients with TEAE	114 (50.9)	59 (50.0)	173 (50.6)
Most common TEAEs†			
COVID-19	34 (15.2)	11 (9.3)	45 (13.2)
Nasopharyngitis	11 (4.9)	5 (4.2)	16 (4.7)
Upper respiratory tract infection	4 (1.8)	6 (5.1)	10 (2.9)
Urinary tract infection	7 (3.1)	1 (0.8)	8 (2.3)
Viral infection	1 (0.4)	4 (3.4)	5 (1.5)
Patients with treatment-related TEAE	14 (6.3)	6 (5.1)	20 (5.8)
Patients with application site reaction	19 (8.5)	6 (5.1)	25 (7.3)
Patients with serious TEAE‡	7 (3.1)	4 (3.4)	11 (3.2)
Patients with TEAE leading to discontinuation	0	1 (0.8)	1 (0.3)

- Ruxolitinib cream was well tolerated
- Treatment-related TEAEs among patients who applied ruxolitinib cream at any time were all mild or moderate (none serious)

Cohort B: TEAE, treatment-emergent adverse event.
† Occurring in ≥3% of patients in any treatment group.
‡ No serious TEAEs were considered by the investigators to be related to treatment.

Conclusion

- ✓ **Improvements in F-VASI responses were observed with continued ruxolitinib cream treatment**
- ✓ **Many patients who reached ≥F-VASI90 were able to maintain durable response for 1 year following withdrawal of ruxolitinib cream**
  - Only 29% of patients who were withdrawn from ruxolitinib cream relapsed (<F-VASI75)
- ✓ **Patients who relapsed upon stopping active treatment, were able to regain responses upon reinitiating ruxolitinib cream**
  - 75%/69% of patients who relapsed following withdrawal, were able to regain F-VASI75/F-VASI90 upon restarting ruxolitinib cream
- ✓ **Ruxolitinib cream was well tolerated over 104 weeks**

Next Steps

- **Phase 2 trial evaluating ruxolitinib cream + phototherapy is ongoing**

Presented at the American Academy of Dermatology (AAD) Annual Meeting
March 17–21, 2023; New Orleans, LA

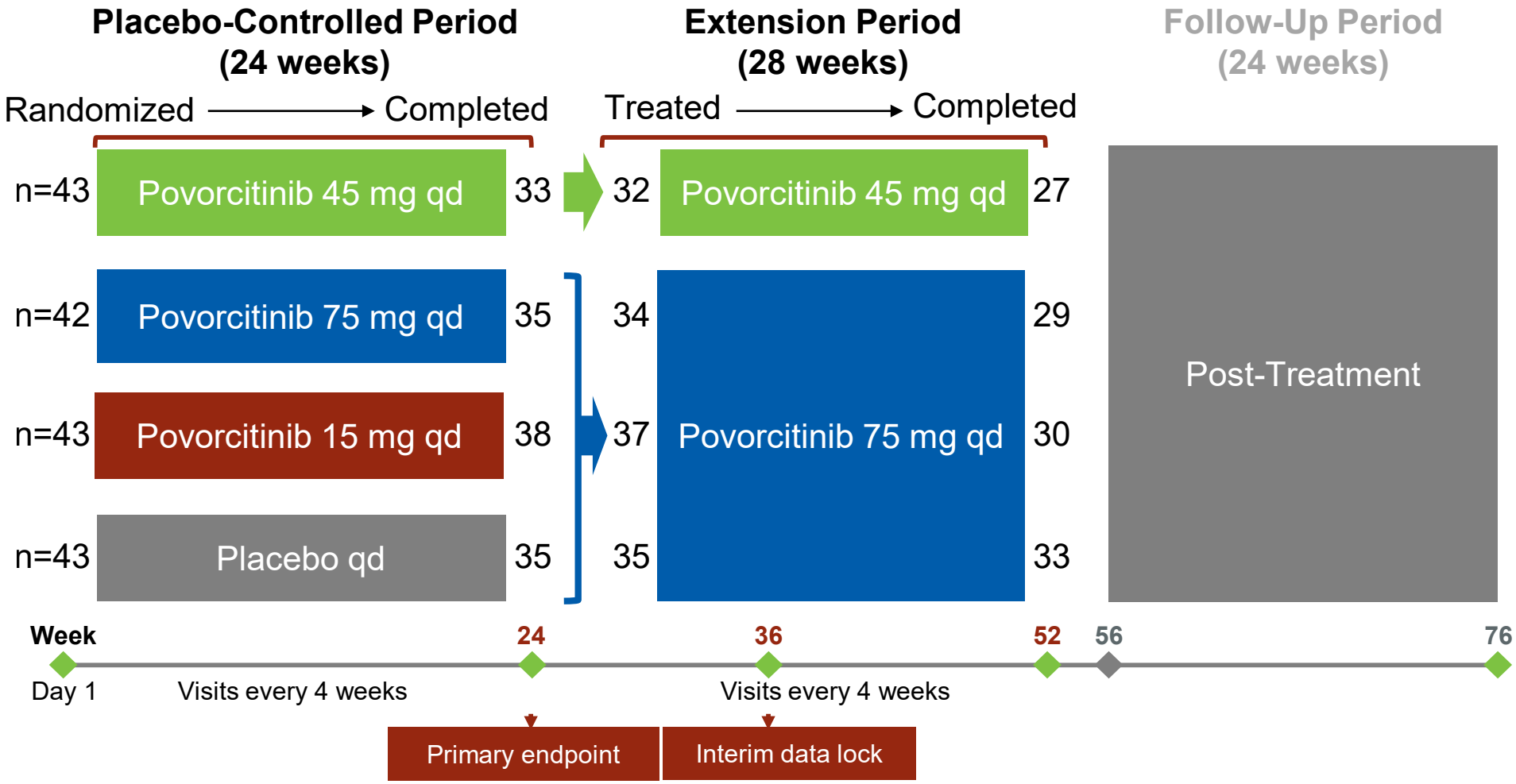
Efficacy and Safety of Povorcitinib for Extensive Vitiligo: Results From a Double-Blinded, Placebo-Controlled, Dose-Ranging Phase 2b Study

Amit G. Pandya, MD,[1,2] Khaled Ezzedine, MD, PhD,[3] Thierry Passeron, MD, PhD,[4,5]
Nanja van Geel, MD, PhD,[6] Kurt Brown, MD,[7] Leandro Santos, MSc,[7] Lois Erskine, PhD,[7]
Kofi Wagya, PhD,[7] Andrew Blauvelt, MD, MBA[8]

[1]University of Texas Southwestern Medical Center, Dallas, TX, USA; [2]Palo Alto Foundation Medical Group, Sunnyvale, CA, USA; [3]Henri Mondor University Hospital and Université Paris-Est Créteil Val de Marne, Paris, France; [4]Centre Hospitalier Universitaire de Nice, Université Côte d'Azur, Nice, France; [5]INSERM U1065, C3M, Université Côte d'Azur, Nice, France; [6]Ghent University Hospital, Ghent, Belgium; [7]Incyte Corporation, Wilmington, DE, USA; [8]Oregon Medical Research Center; Portland, OR, USA

Study Design (NCT04818346)

Patient population:
- Adults 18–75 years old
- Nonsegmental vitiligo
- Vitiligo-affected BSA*:
  - Total body ≥8%
  - Face ≥0.5%



BSA, body surface area; F-VASI, facial VASI; F-VASI50/75, ≥50%/≥75% reduction from baseline in F-VASI; qd, once daily; TEAE, treatment-emergent adverse event; T-VASI, total VASI; T-VASI50, ≥50% reduction from baseline in T-VASI; VASI, Vitiligo Area Scoring Index.
* Total and facial BSA were locally assessed. † Week 24 assessment was the primary endpoint.

Patient Demographics and Clinical Characteristics at Baseline

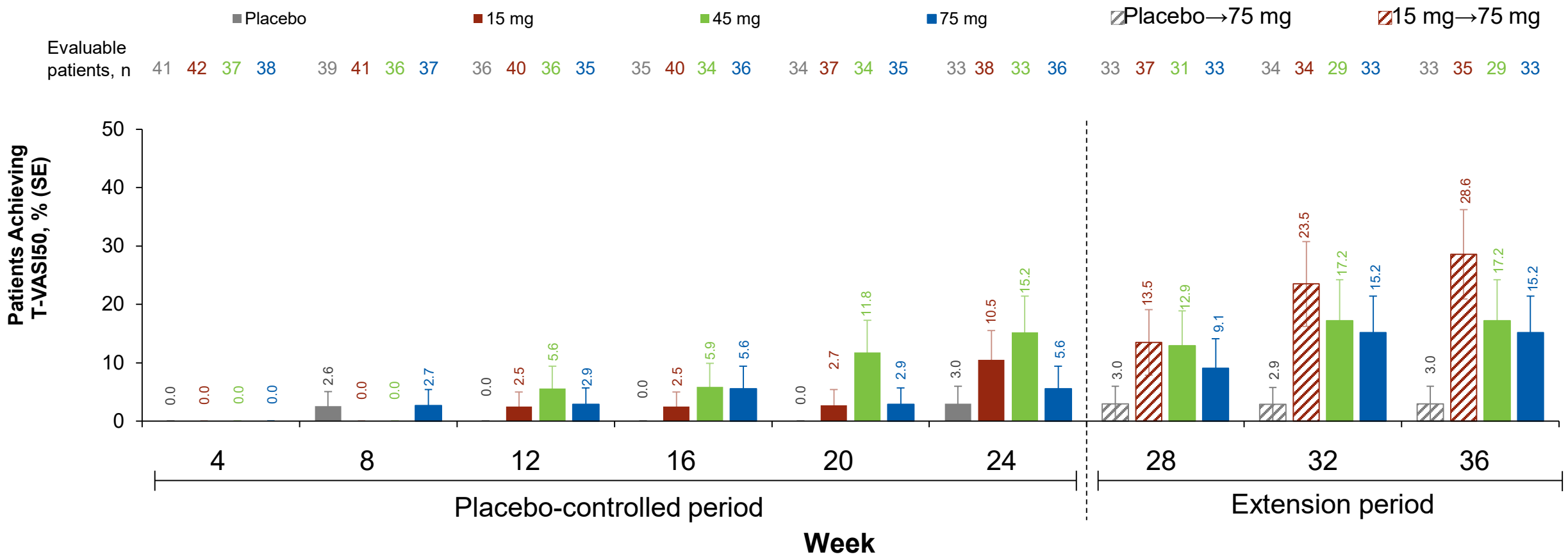
Characteristic	Placebo (n=43)	Povorcitinib 15 mg (n=43)	Povorcitinib 45 mg (n=43)	Povorcitinib 75 mg (n=42)	Total (N=171)
Age, median (range), y	51.0 (24–72)	45.0 (23–67)	51.0 (25–72)	52.5 (24–74)	50.0 (23–74)
Female, n (%)	24 (55.8)	29 (67.4)	21 (48.8)	19 (45.2)	93 (54.4)
Race, n (%)					
White	34 (79.1)	32 (74.4)	38 (88.4)	28 (66.7)	132 (77.2)
Asian	2 (4.7)	4 (9.3)	0	7 (16.7)	13 (7.6)
Black	2 (4.7)	3 (7.0)	1 (2.3)	3 (7.1)	9 (5.3)
Hispanic, n (%)	8 (18.6)	6 (14.0)	11 (25.6)	7 (16.7)	32 (18.7)
Fitzpatrick skin type, n (%)					
I–III	28 (65.1)	26 (60.5)	35 (81.4)	25 (59.5)	114 (66.7)
IV–VI	15 (34.9)	17 (39.5)	8 (18.6)	17 (40.5)	57 (33.3)

Characteristic	Placebo (n=43)	Povorcitinib 15 mg (n=43)	Povorcitinib 45 mg (n=43)	Povorcitinib 75 mg (n=42)	Total (N=171)
Baseline F-VASI, mean (SD)	1.5 (0.8)	1.3 (0.8)	1.3 (0.8)	1.1 (0.7)	1.3 (0.8)
Baseline T-VASI, mean (SD)	28.3 (21.5)	27.1 (20.1)	23.6 (19.8)	22.7 (14.2)	25.5 (19.1)
Duration of disease, mean (SD), y	19.5 (14.0)	17.6 (13.0)	19.9 (15.5)	20.5 (13.7)	19.4 (14.0)
Family history of vitiligo, n (%)	15 (34.9)	9 (20.9)	11 (25.6)	14 (33.3)	49 (28.7)
Thyroid disorders, n (%)	11 (25.6)	12 (27.9)	12 (27.9)	12 (28.6)	47 (27.5)
Previous therapy,* n (%)					
Topical corticosteroid	18 (41.9)	24 (55.8)	21 (48.8)	25 (59.5)	88 (51.5)
Topical calcineurin inhibitor	14 (32.6)	13 (30.2)	17 (39.5)	20 (47.6)	64 (37.4)
Any phototherapy	20 (46.5)	17 (39.5)	13 (30.2)	27 (64.3)	77 (45.0)

* Patients could have used multiple previous lines of therapy.

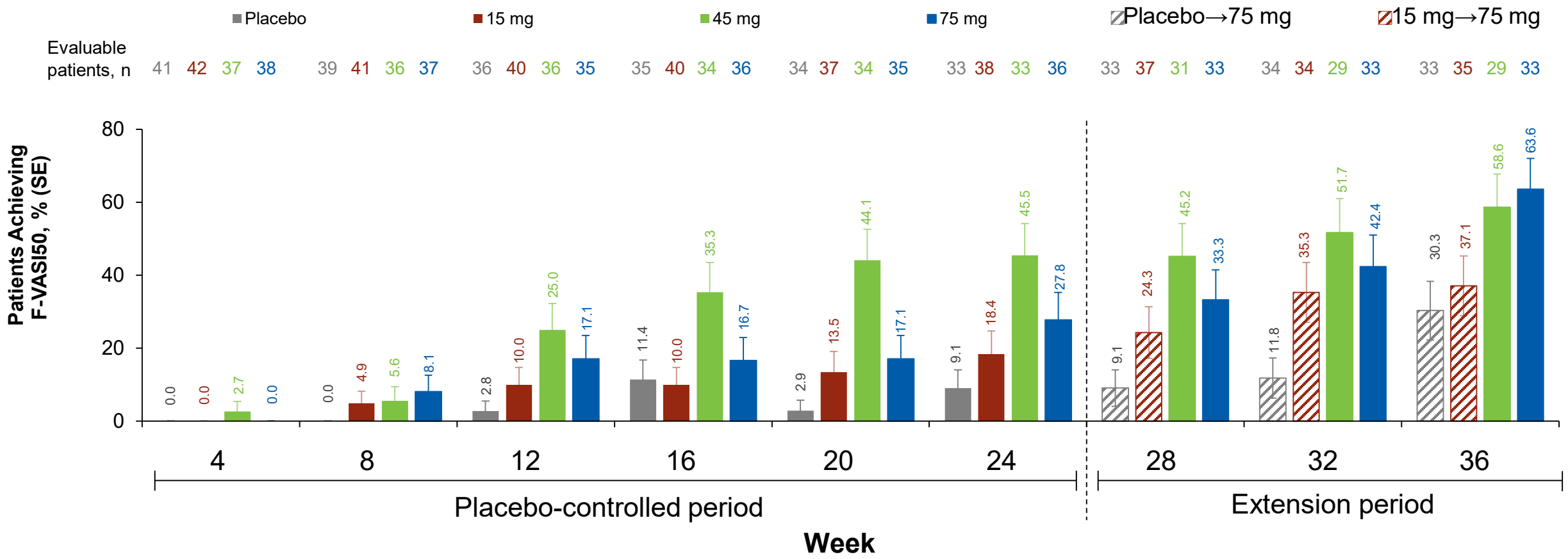
T-VASI50

- More patients who received povorcitinib achieved T-VASI50 vs placebo at Week 24 and continued to improve through Week 36 of treatment



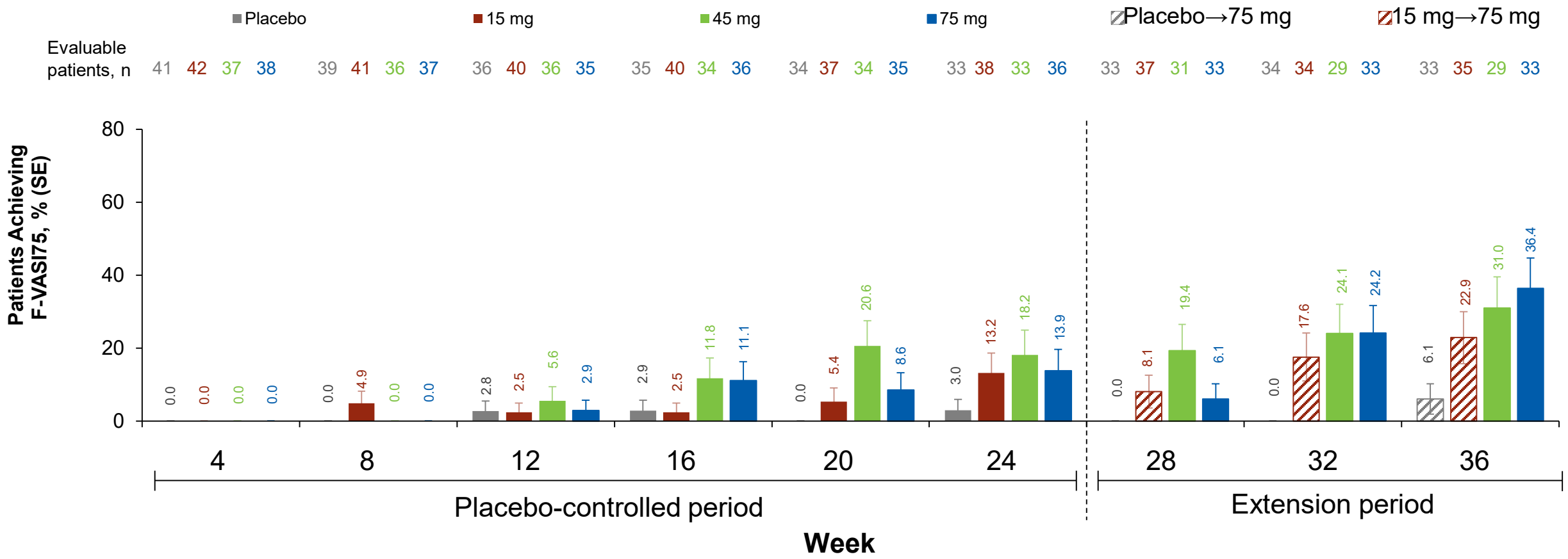
F-VASI50

- More patients who received povorcitinib achieved F-VASI50 vs placebo at Week 24 and continued to improve through Week 36 of treatment



F-VASI75

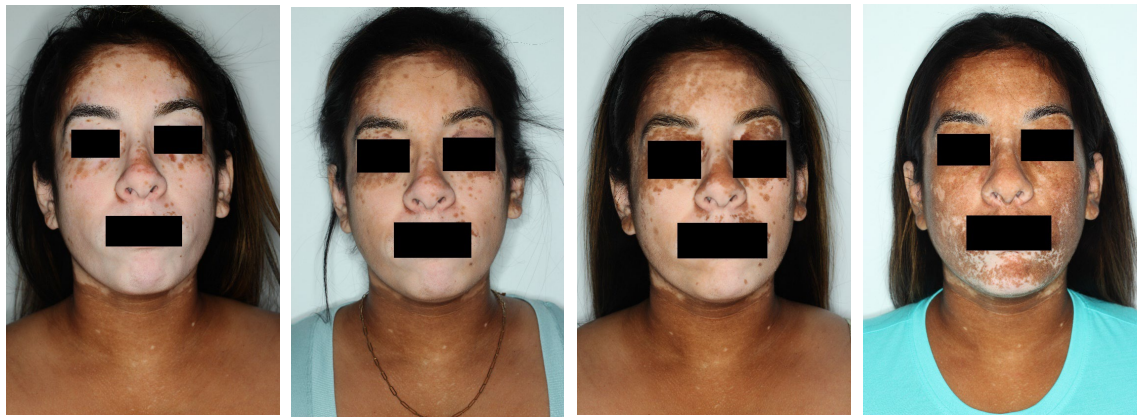
- More patients who received povorcitinib achieved F-VASI75 vs placebo at Week 24 and continued to improve through Week 36 of treatment



Patient Photographs

Patient 1

Baseline	Week 12	Week 24	Week 36
	Povorcitinib 15 mg		Povorcitinib 75 mg

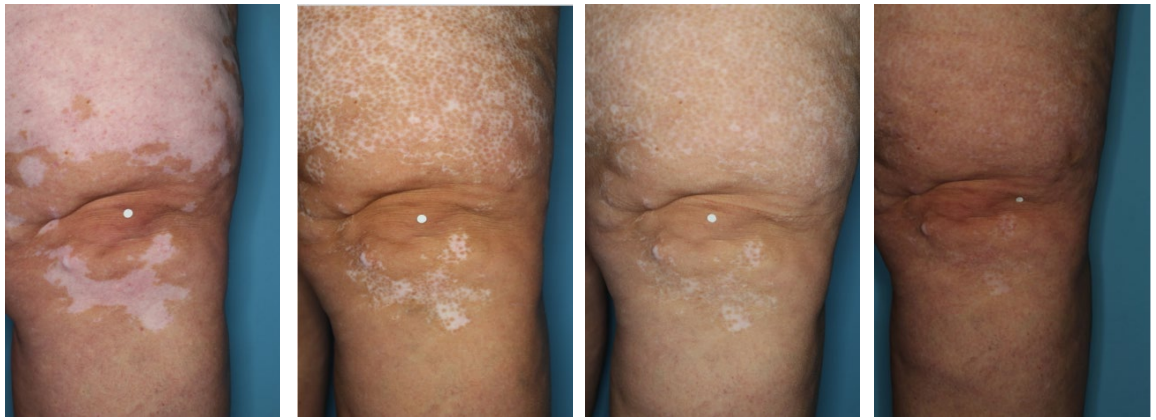


F-VASI percentage change from baseline:

Week 12	Week 24	Week 36
–16.7	–44.4	–85.2

Patient 2

Baseline	Week 12	Week 24	Week 36
	Povorcitinib 15 mg		Povorcitinib 75 mg



T-VASI percentage change from baseline:

Week 12	Week 24	Week 36
–14.6	–31.8	–64.8

Safety

TEAEs in Placebo-Controlled Period (Week 24)

- Oral povorcitinib was generally well tolerated, and no serious TEAEs were considered related to treatment; no new safety signals were observed after Week 24

		Povorcitinib			
	Placebo (n=42)	**15 mg (n=43)**	**45 mg (n=41)**	**75 mg (n=42)**	**Total (n=126)**
Patients with TEAE, n (%)	24 (57.1)	29 (67.4)	30 (73.2)	35 (83.3)	94 (74.6)
Most common TEAEs, n (%)					
COVID-19	5 (11.9)	8 (18.6)	8 (19.5)	5 (11.9)	21 (16.7)
Headache	5 (11.9)	7 (16.3)	1 (2.4)	5 (11.9)	13 (10.3)
Fatigue	2 (4.8)	3 (7.0)	3 (7.3)	6 (14.3)	12 (9.5)
Blood creatine phosphokinase increased	3 (7.1)	3 (7.0)	3 (7.3)	4 (9.5)	10 (7.9)
Acne	0	0	3 (7.3)	6 (14.3)	9 (7.1)
Grade 3 TEAE, n (%)	4 (9.5)	3 (7.0)	5 (12.2)	5 (11.9)	13 (10.3)
TEAE leading to discontinuation, n (%)	2 (4.8)	2 (4.7)	2 (4.9)	3 (7.1)	7 (5.6)
Serious TEAE, n (%)	1 (2.4)	0	1 (2.4)	1 (2.4)	2 (1.6)
Fatal TEAE, n (%)	0	0	0	0	0

Conclusions

- This is the first report of povorcitinib, an oral selective JAK1 inhibitor, in patients with extensive nonsegmental vitiligo
- Povorcitinib was associated with substantial repigmentation in patients with extensive nonsegmental vitiligo after 24 weeks of once-daily treatment
- Continued improvement was seen through 36 weeks of treatment with povorcitinib during the extension period
- All doses of povorcitinib were generally well tolerated, with a favorable safety profile; there were few grade ≥3 or serious TEAEs

Advances in the Treatment of Vitiligo

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Staff Dermatologist, Palo Alto Foundation Medical Group, Sunnyvale, California, U.S.A.
Adjunct Professor, Department of Dermatology
University of Texas Southwestern Medical Center, Dallas, Texas, U.S.A.

Specializing in vitiligo and pigmentary disorders

- Specialty in vitiligo and pigmentary disease
  - ~80 vitiligo patients a month
  - ~20% new / 80% existing
  - 50% with facial vitiligo / visible vitiligo
  - 100% of patients currently receiving treatment

- Very active within vitiligo community
  - Global Vitiligo Foundation President
  - Vitiligo International Symposium organizer
  - World Vitiligo Day speaker
  - My Vitiligo Team Editor

Palo Alto Foundation Medical Group,
Sunnyvale, California

Dermatology clinic specializing in vitiligo and pigmentary disease

Real-world impact of vitiligo on patients

- Psychological impact
  - Anxiety
  - Depression
  - Suicidal ideation
  - Body dysmorphic disorder
- Impact on careers, seeking jobs
- Impact on intimate relationships or with friends
- Economic burden
  - Multiple doctor visits
  - Phototherapy 3x/week
  - Medication cost
  - Lost time at work

Psychosocial Comorbidities in Patients With Vitiligo: A Systematic Literature Review

Ezzedine K, et al, Am J Clin Dermatol 2021

Despite psychological impact, few patients are being treated

Few vitiligo patients are being treated due to:

- Lack of approved therapies and/or clinical data
- Lack of compliance with treatments
  - Time in office, frequency of visits
- Burden with cost
- HCPs are not familiar with vitiligo treatment

Drivers of patients seeking treatment:

- Extent of vitiligo
- Location of lesion (face, other visible areas)
- Number of years with vitiligo
- Access to vitiligo treatment center
- Insurance coverage

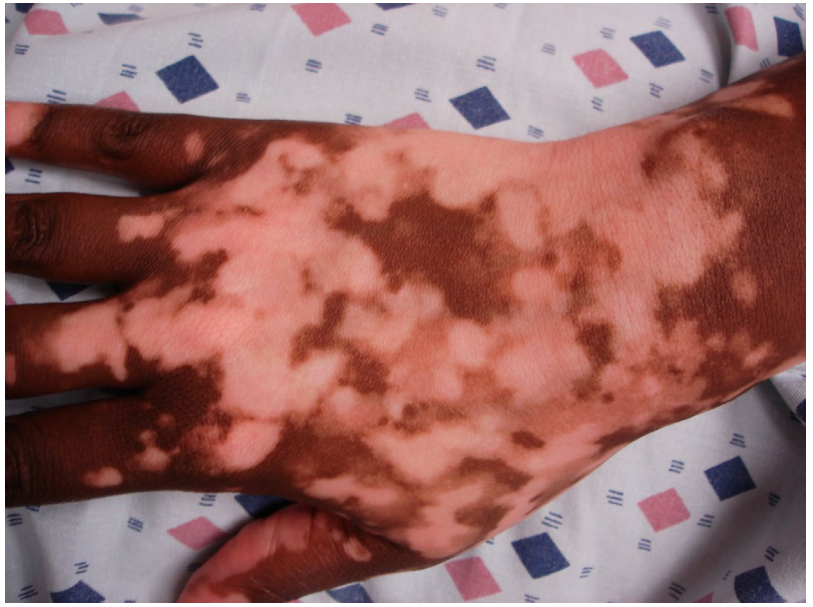
2-3 million patients with vitiligo (0.8% of population) in the U.S.

<200,000 patients being treated

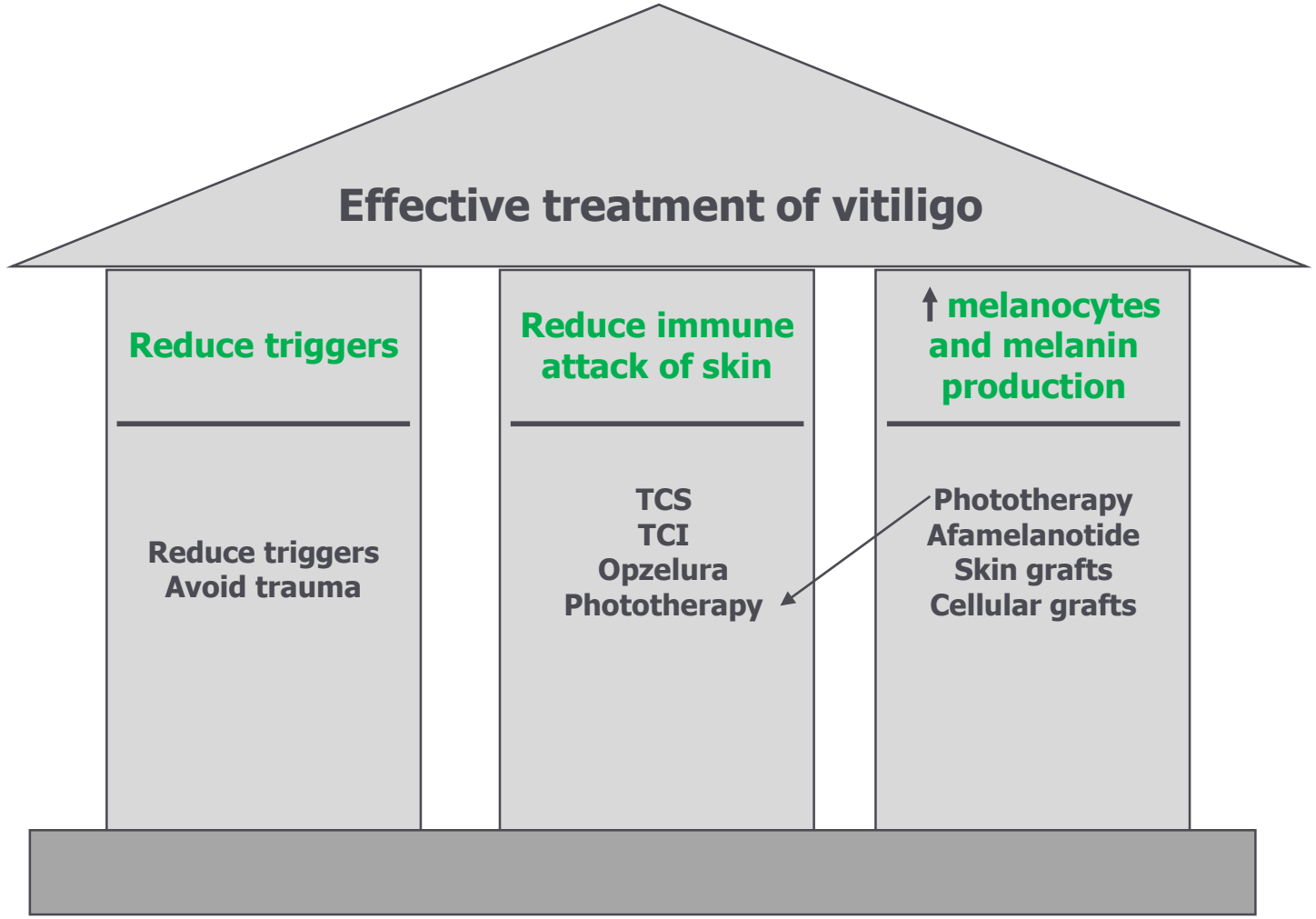
Deciding on the best treatment plan for patients

Factors to think about:

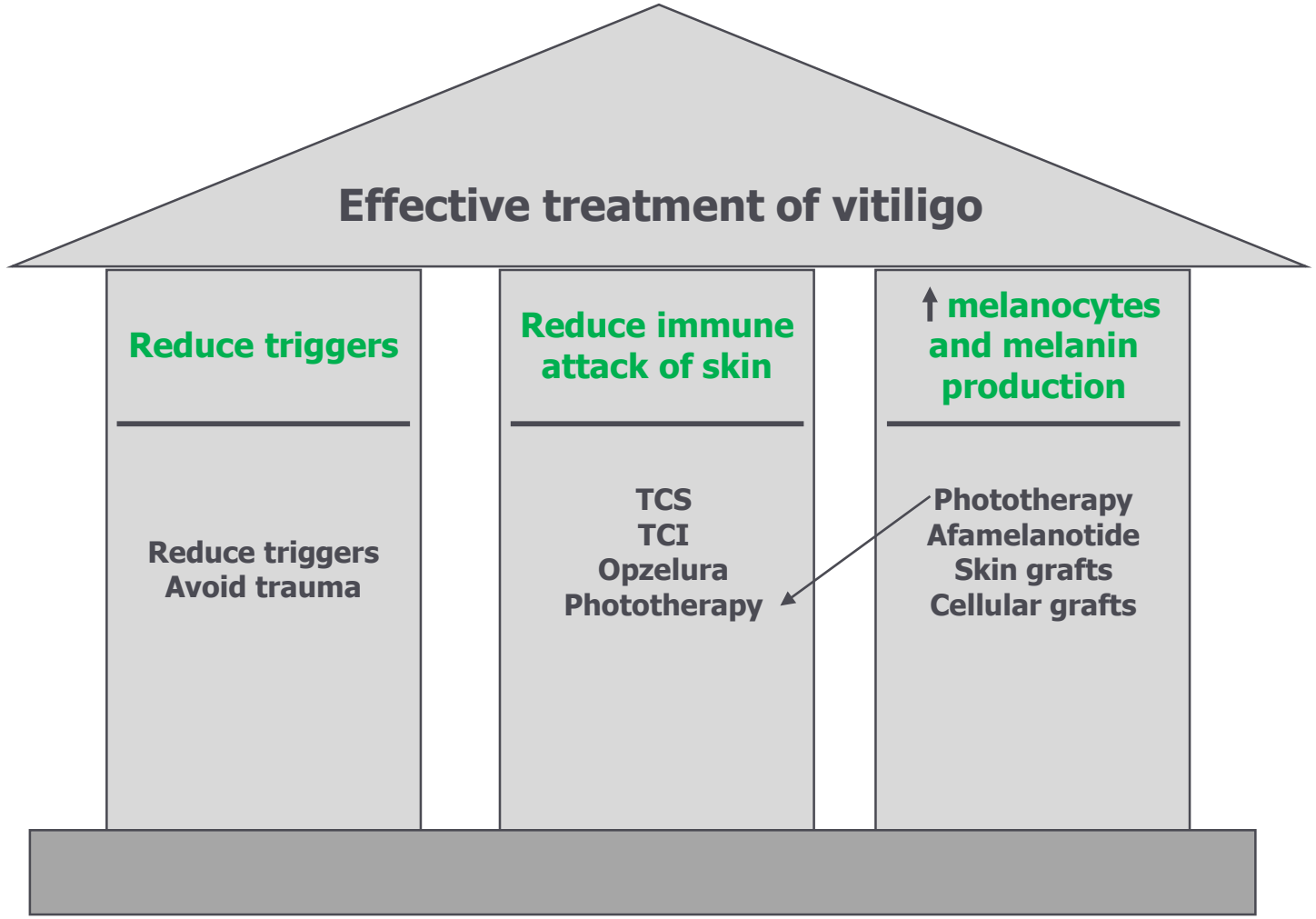
- Treatment goals (stabilize vitiligo? 100% repigmentation?)
  - What are patients most bothered by?
  - Expectations from patients
  - Location to be treated (face, hands, total body, etc.)
- Past experience with treatments
- Likelihood of vitiligo improving
- Logistics/Cost
  - Time that patients can spend on treatment
  - Patient's ability to afford treatment
- Age, cultural background, ethnicity



Three pillars for the effective treatment of vitiligo



Opzelura is a clear choice for first line therapy for vitiligo



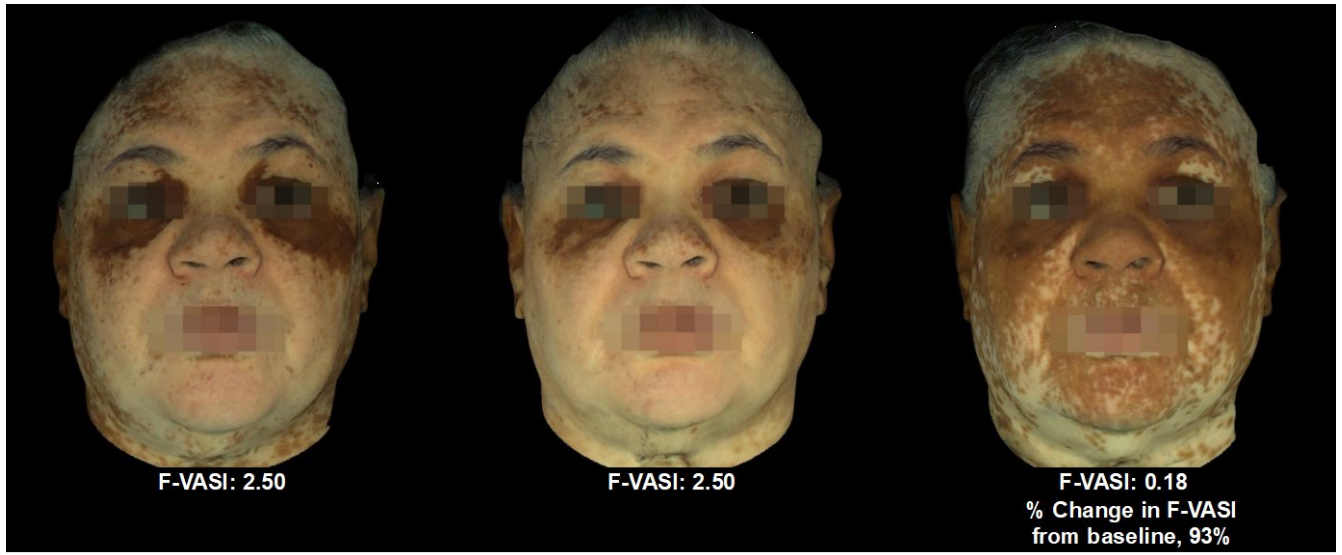
Opzelura™ (ruxolitinib) cream 1.5%

~90% of patients are candidates for Opzelura

Successfully managing and treating vitiligo with Opzelura

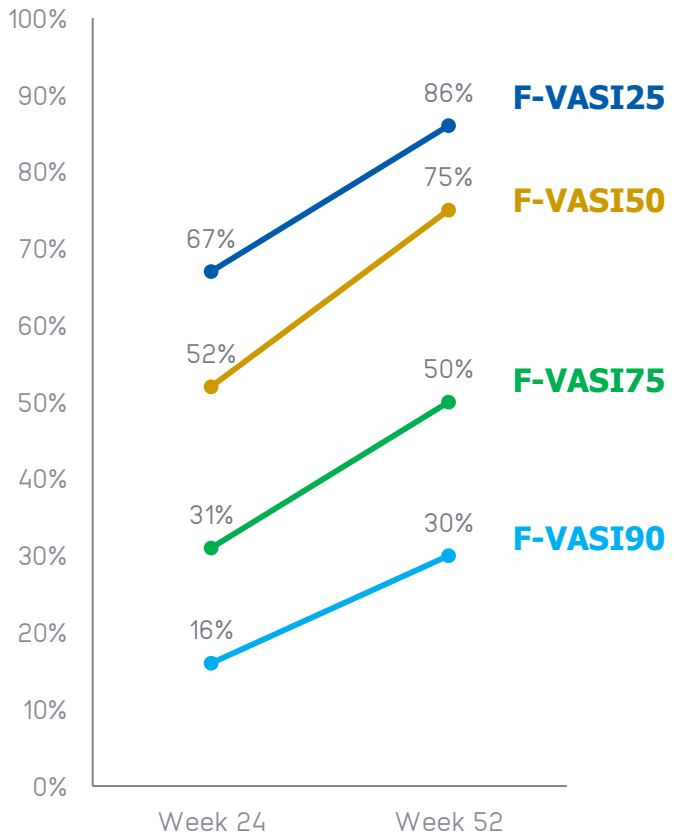
Setting the right expectations

- ✓ Repigmentation takes time
  - Melanocytes need time to migrate and repigment
  - Speed of repigmentation depends on area of body, age, length of diagnosis
  - Active vs stable disease
- ✓ Percent repigmentation varies
- ✓ Importance of compliance with therapy

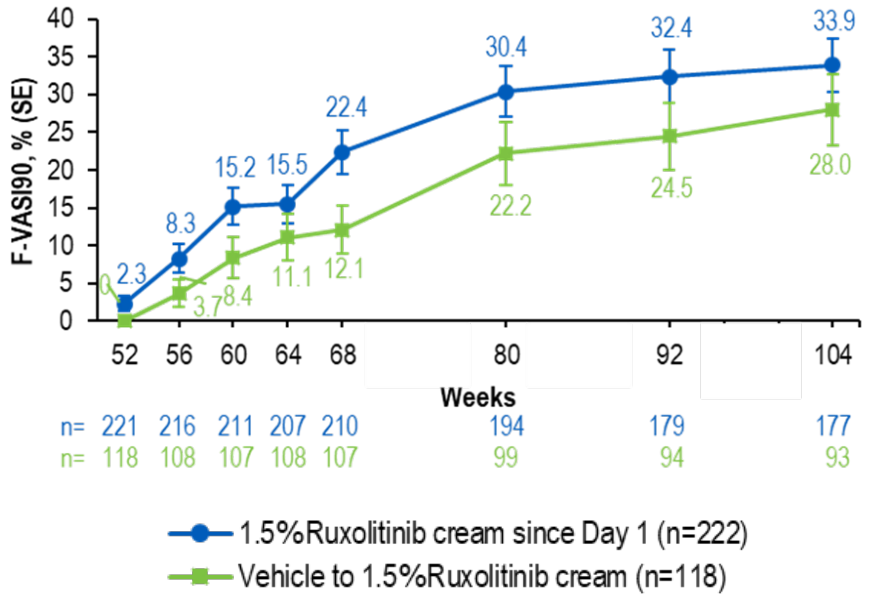


Majority of patients likely to respond to Opzelura

F-VASI responses after 52 weeks of Opzelura treatment



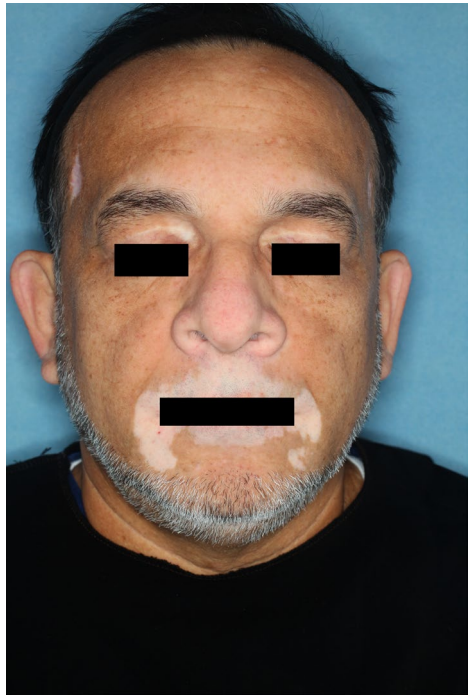
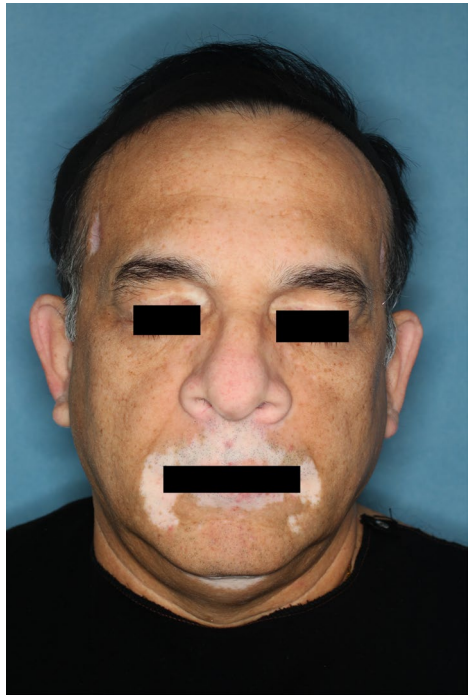
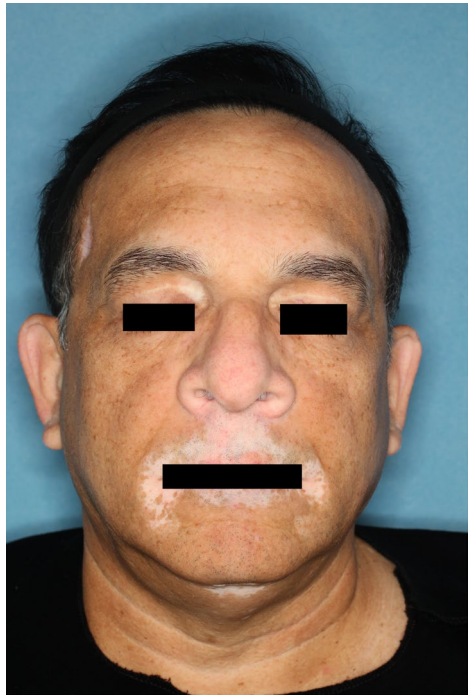
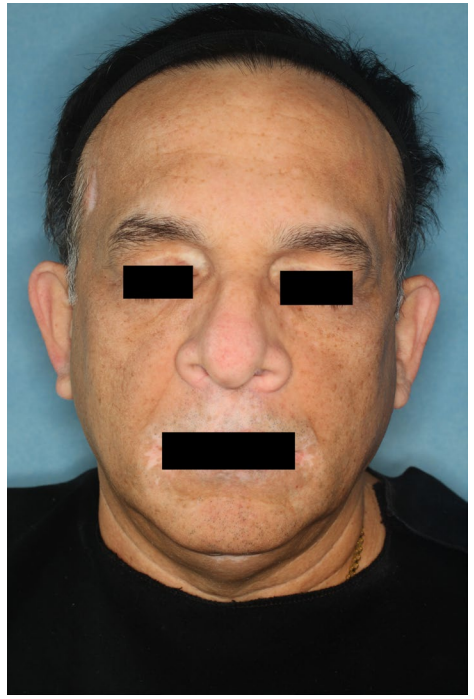
Patients who did not achieve F-VASI90 by Wk 52 continued to improve



- ✓ Many patients can continue to respond with longer treatment
- ✓ Responses take time and can vary by patient
- ✓ If F-VASI25 is not reached at Week 24, could add phototherapy to provide a "boost"

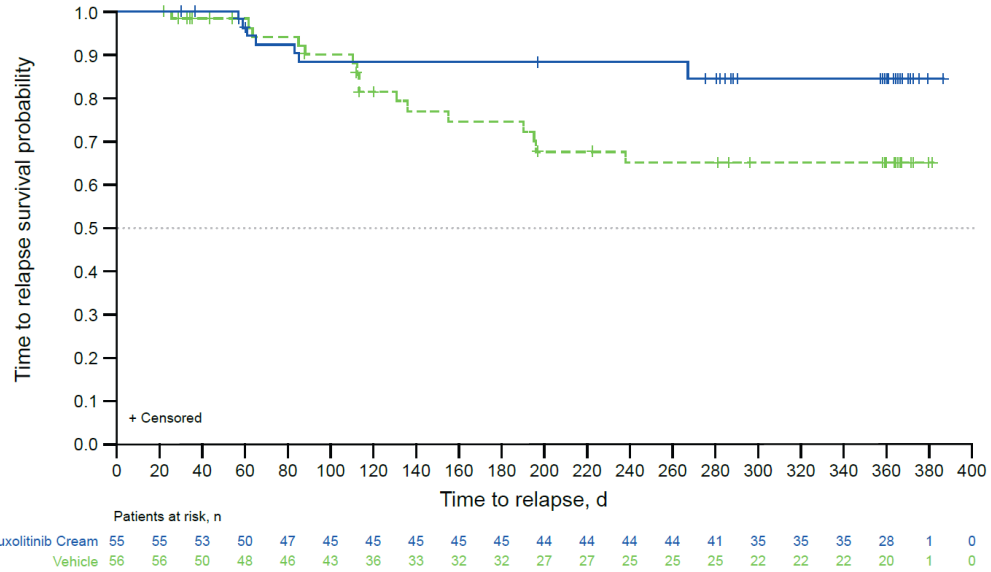
- 1st visit at Week 24
- Follow-on visits every 3 months

TRuE-V trial participant: Continued improvement thru 104 weeks

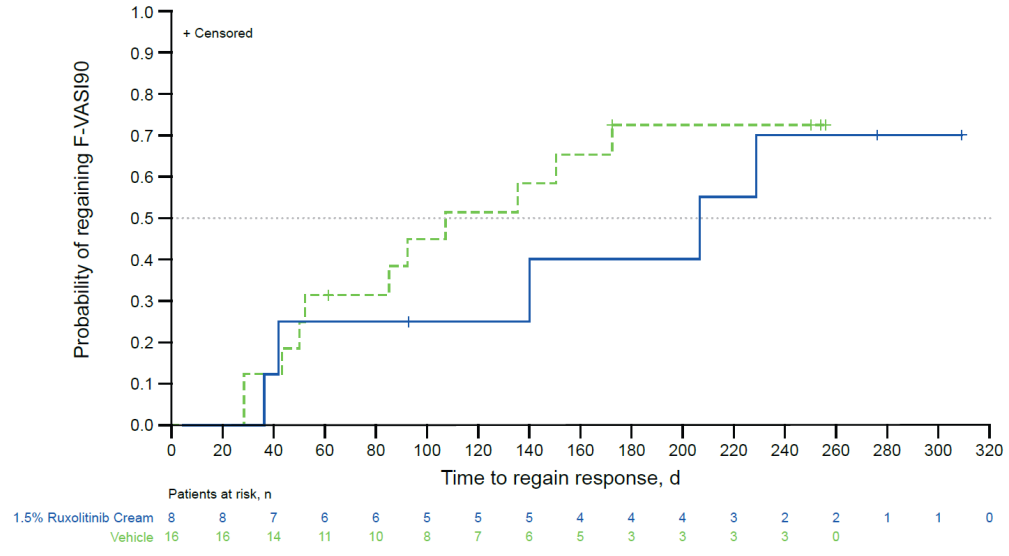
Baseline	Week 12	Week 24	Week 52	Week 104
				
F-VASI: 0.59	F-VASI: 0.57 % Chg from B_0: -3%	F-VASI: 0.33 % Chg from B_0: -44%	F-VASI: 0.13 % Chg from B_0: -78%	F-VASI: 0.1 % Chg from B_0: -83%

Multiple possibilities for maintenance once F-VASI90 is achieved

Kaplan-Meier curve of the time to relapse (F-VASI<75)



Kaplan-Meier curve of the time to regain ≥F-VASI90 response



Patients who reach ≥F-VASI90 will have options:

- ✓ **Stay on Opzelura:** Patient has a high likelihood of maintaining an excellent response
- ✓ **Withdraw from Opzelura:**
  - Patient has ~30% chance of returning to level of depigmentation that is likely undesirable to the patient
  - However, if patient relapses (or starts to see depigmentation), a high response can be regained upon re-initiating treatment

How has Opzelura changed clinical practice?

Patient excitement and motivation are high

Patients are proactively scheduling appointments to ask about Opzelura

Currently have a 4 to 5-month backlog for new patient appointments

What does this mean for Physicians?

1. Physicians need to provide patients education on mechanism of disease, need for maintenance and LT application

2. Physicians can now offer patients an FDA-approved therapy backed by confirmed clinical data

3. Most patients should be able to access Opzelura through their insurance plans

Incyte

Opzelura is game-changing for vitiligo patients

Markedly induces acne clearance with prolonged remission;
SOC for deep, painful acne cysts/nodules

Durable remissions and significant reductions in hospital stays;
SOC for moderate-to-severe psoriasis

Dramatically reduces disease and symptom severity;
SOC for moderate-to-severe atopic dermatitis

First and only FDA-approved therapy for repigmentation
Breakthrough opportunity to improve patients' lives

Other exciting therapies in development for vitiligo

Light therapy + Opzelura

Targets melanin production & inflammation

Potential to accelerate response in patients

Povorcitinib and other oral JAK inhibitors

Targets inflammation

Potential to treat increased BSA compared to topicals

Auremolimab (IL-15Rβ) mAb

Targets T_{RM} as potential disease-modifying agent

Potential to eliminate T_{RM} cells and induce lasting remission

Bergqvist C, Ezzedine K. Vitiligo: A Review. Dermatology 2020;236:571-592. doi: 10.1159/000506103;

Q&A

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