

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, MBA⁸

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

Presenting Author Disclosures

- Investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte, and Pfizer
- Consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte, Pfizer, TWi, Viela Bio, and Villaris
- Holds stock options for Tara Medical and Zerigo Health

Background

- Vitiligo is a chronic autoimmune disease that targets melanocytes, resulting in patches of skin depigmentation¹
- Disease pathogenesis is largely regulated by interferon- γ activation of the JAK signaling pathway²
- Povorcitinib is an oral, small-molecule, selective JAK1 inhibitor with potential activity in the treatment of nonsegmental vitiligo
- **Objective:** To evaluate the efficacy and safety of povorcitinib in patients with extensive nonsegmental vitiligo in a phase 2b trial (NCT04818346)

Study Design (NCT04818346)

Patient population:

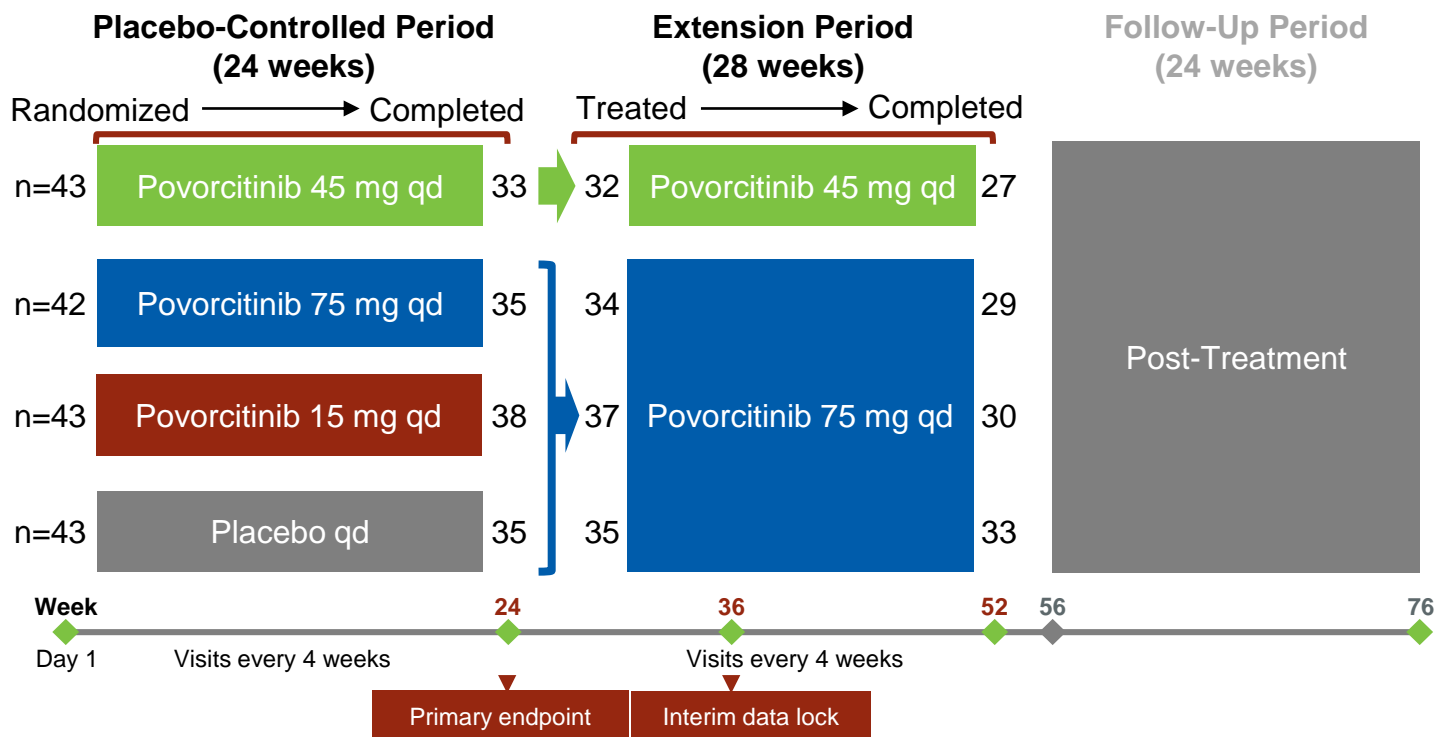
- Adults 18–75 years old
- Nonsegmental vitiligo
- Vitiligo-affected BSA*:
 - Total body $\geq 8\%$
 - Face $\geq 0.5\%$
- VASI score:
 - T-VASI ≥ 8
 - F-VASI ≥ 0.5

Efficacy assessments:

- % change from baseline in T-VASI[†]
- % patients achieving T-VASI50, F-VASI50, and F-VASI75

Safety assessments:

Incidence of TEAEs



BSA, body surface area; F-VASI, facial VASI; F-VASI50/75, $\geq 50\%/ \geq 75\%$ reduction from baseline in F-VASI; qd, once daily; TEAE, treatment-emergent adverse event; T-VASI, total VASI; T-VASI50, $\geq 50\%$ 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 | Povorcitinib | | | | Total (N=171) |
|------------------------------|-------------------|-----------------|-----------------|-----------------|------------------|
| | Placebo (n=43) | 15 mg (n=43) | 45 mg (n=43) | 75 mg (n=42) | |
| 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 | Povorcitinib | | | | Total (N=171) |
|-----------------------------------|-------------------|-----------------|-----------------|-----------------|------------------|
| | Placebo (n=43) | 15 mg (n=43) | 45 mg (n=43) | 75 mg (n=42) | |
| 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.