PRURIGO NODULARIS

NCT06516952 and NCT06516965

Incyte Dermatology

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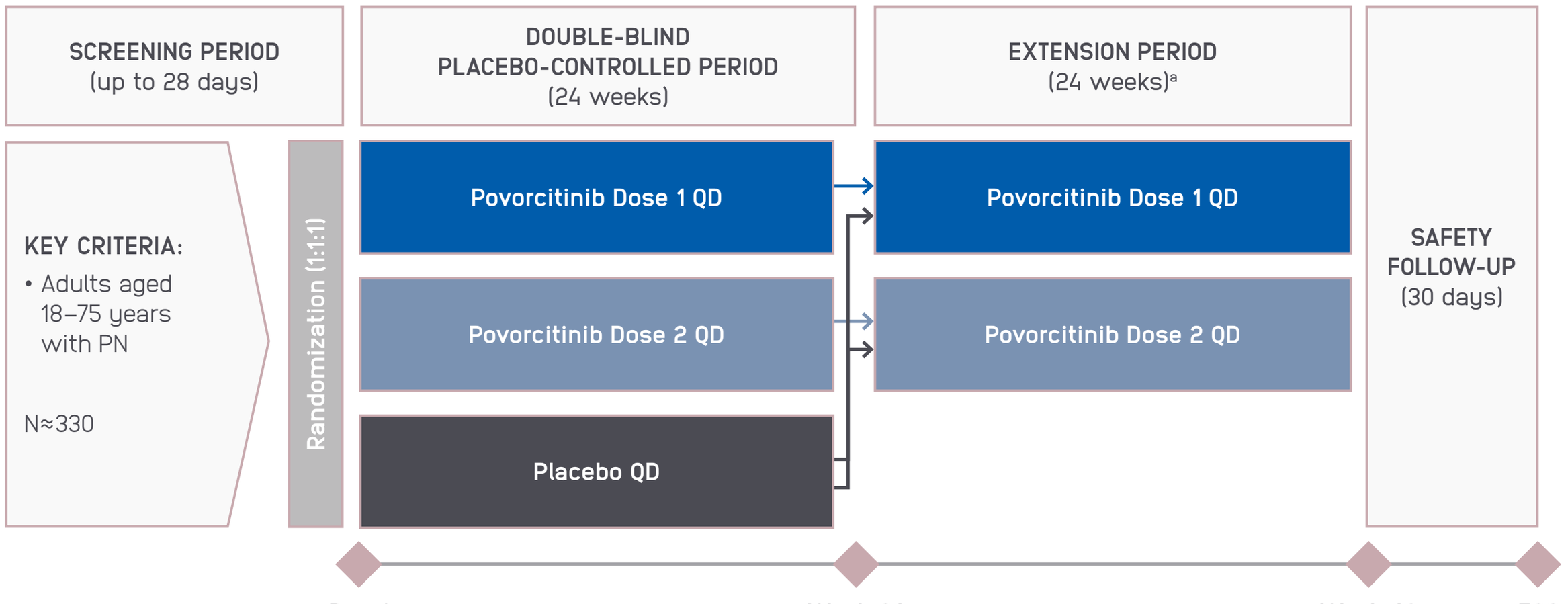
Two Identical Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies of Povorcitinib in Patients With Moderate-to-Severe Prurigo Nodularis

STOP-PN1 & STOP-PN2



[a]The investigator and participant will remain blinded to povorcitinib dose as well as prior treatment assignment.

1

PRIMARY ENDPOINT:

- Proportion of patients who achieve Itch NRS4[b] and IGA-CPG-S-TS[c] at week 24

2

SELECT SECONDARY ENDPOINTS:

- Proportions of patients who achieve:
  - Itch NRS4[b] at week 24
  - IGA-CPG-S-TS[c] at week 24
  - Itch NRS4[b] at week 4
- Change from baseline in DLQI score
- Change from baseline in Skin Pain NRS score
- Change from baseline in FACIT-F score
- Frequency and severity of AEs

For more information, please visit: https://www.clinicaltrials.gov/study/NCT06516952

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[b]Defined as a ≥4-point improvement (reduction) in Itch NRS score from baseline. [c]Defined as IGA-CPG-S score of 0 or 1 with a ≥2-grade improvement from baseline.

SELECT INCLUSION CRITERIA

- Adults (aged 18–75 years) with clinical diagnosis of PN for ≥3 months before screening
- ≥20 pruriginous lesions on ≥2 different body regions (both legs, and/or both arms, and/or trunk) at screening and baseline
- Itch NRS score ≥7[d]
- IGA-CPG-S score ≥3
- History of failure[e] or intolerance, or contraindication to, prior PN therapy

SELECT EXCLUSION CRITERIA

- Chronic pruritus due to a condition other than PN or neuropathic and psychogenic pruritus
- Active AD lesions for ≥3 months before screening

[d]During the 7 days prior to day 1/baseline. [e]Patients with a history of failure to any topical or systemic JAK or TYK2 inhibitor as treatment for PN or any inflammatory disease are not eligible.

The efficacy and safety of the investigational compound discussed have not been established.
There is no guarantee that this compound will become commercially available for the use under investigation.

For more information, search for study NCT06516952 and study NCT06516965 on **IncyteClinicalTrials.com** or contact us at **clintrials@incyte.com**

AD, atopic dermatitis; AEs, adverse events; DLQI, Dermatology Life Quality Index; EOS, end of study; EOT, end of treatment; FACIT-F, Functional Assessment of Chronic Illness Therapy - Fatigue; IGA-CPG-S, Investigator's Global Assessment for Stage of Chronic Prurigo; IGA-CPG-S-TS, Investigator's Global Assessment for Stage of Chronic Prurigo treatment success; JAK, Janus kinase; NRS, numeric rating scale; NRS4, ≥4-point improvement in Itch NRS score; PN, prurigo nodularis; QD, once daily; TYK2, tyrosine kinase 2.

ClinicalTrials.gov websites, available at: https://clinicaltrials.gov/study/NCT06516952 and https://clinicaltrials.gov/study/NCT06516965; accessed August 27, 2024. Data on file, Incyte Corporation.

This information is current as of August 27, 2024