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Study PAS-004-103
Initial cNF and PN clinical data

November 13, 2026

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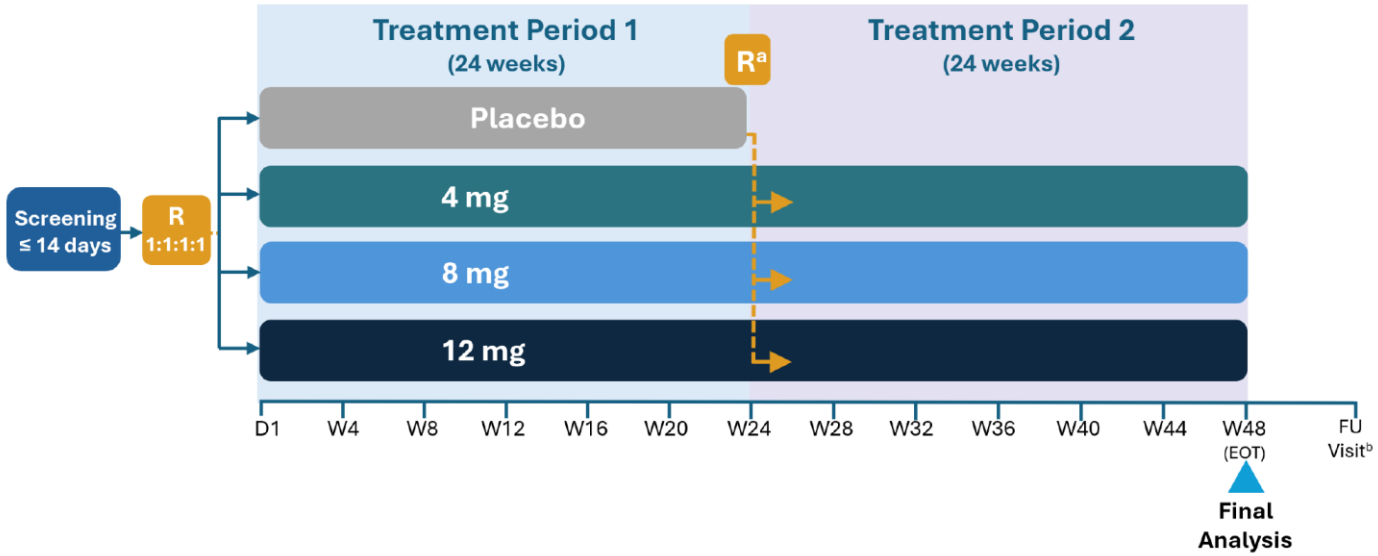
PAS-004-201: Planned double-blind, placebo-controlled Phase 2

IND OPEN

FDA DDD: safe to proceed

Phase 2 in adults with NF1-associated cNF · approximately 200 participants · 48 weeks of blinded treatment

Study design and details still under discussion — schematic reflects the current plan and may change



Trial schematic. At Week 24 participants on placebo are re-randomized 1:1:1 to 4, 8 or 12 mg; those on active treatment continue at the same dose and the blind is maintained.

DESIGN

n = 200 participants

Randomized 1:1:1:1
placebo or 4, 8 or 12 mg once daily

24 + 24 weeks
placebo-controlled, then all active with re-randomization of placebo

Screening ≤ 14 days
4-week safety follow-up

Primary endpoint
safety and tolerability over 24 weeks

Independent DMC

WHAT IS MEASURED

- Ten Target cNF per participant, with at least two on the face
- Length and width by digital calipers and height by ruler, measured in triplicate, giving volume, surface area and height
- 2D photography for lesion identity; optional 3D photography

WHAT IS ASSESSED CLINICALLY

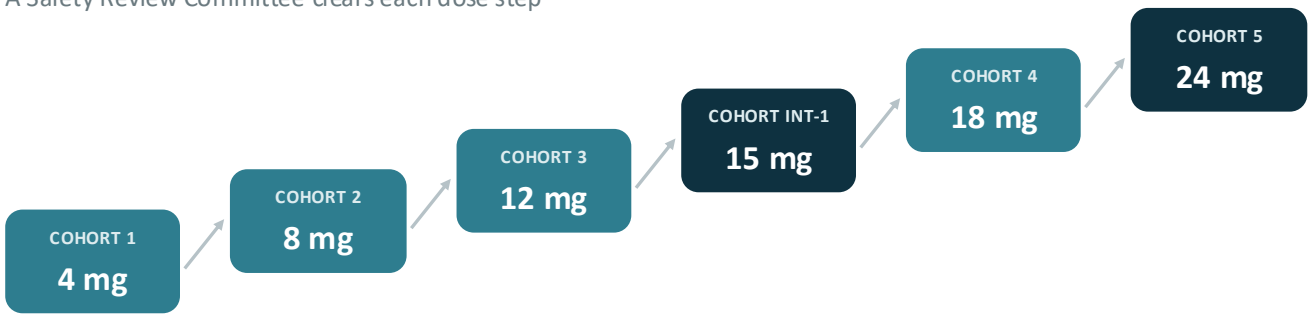
- cNF-specific Investigator Global Assessment of Severity (IGA-S) as a secondary endpoint, with IGA-C for change
- Patient-reported outcome tools — PGI-S for severity and PGI-C for change

PAS-004-103: Global 3+3 Dose Escalation

Phase 1/1b, open-label, 3+3 dose-escalation study in adults with NF1 and symptomatic plexiform neurofibroma · cutaneous neurofibroma is a prespecified substudy

DOSE ESCALATION

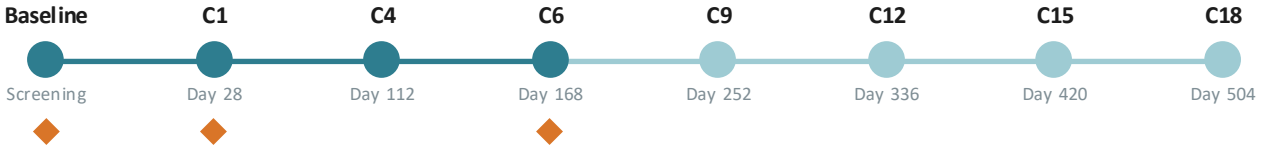
A Safety Review Committee clears each dose step



19 participants enrolled to the cut-off (3 per cohort; 18 mg n = 4)
Cohort INT-1 (15 mg) and Cohort 5 (24 mg) added via amendment

WHEN CNF ARE MEASURED

Cutaneous neurofibroma substudy · digital calipers, in triplicate · ◆ cNF resected for pharmacodynamics at Baseline, C1 and after C6



WHEN PN ARE MEASURED

Target PN volume by volumetric MRI · blinded independent central read · REiNS criteria · same scanner and field strength as Baseline



Teal = Part A core (6 cycles) · light = optional treatment extension to 18 cycles

FIVE SITES, THREE COUNTRIES

All cNF measurements made by the site investigator



UNITED STATES

1. University of Alabama at Birmingham — Birmingham, AL

AUSTRALIA

2. Royal North Shore Hospital — St Leonards, NSW
3. Peter MacCallum Cancer Centre — Melbourne, VIC

SOUTH KOREA

4. Asan Medical Center — Seoul
5. Severance Hospital, Yonsei — Seoul

No regulatory standard exists for measuring cNF or defining cNF response

Four programs, four instruments, four geometries — the response definitions are not interchangeable

Selumetinib[1]

Sponsor Investigator-initiated trial (UAB, NCI)

Instrument analogue calipers

Geometry volume = L × W × H (cube)

Response criteria ≥20% volume reduction

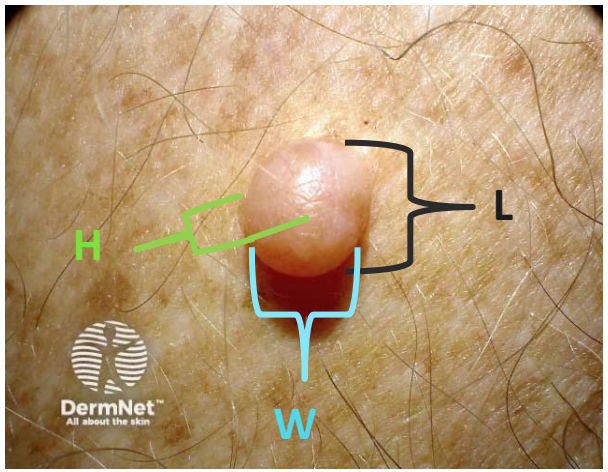
Mirdametinib[2]

Sponsor Investigator-initiated trial (JHU)

Instrument analogue calipers

Geometry longest diameter only

Response criteria ≥25% reduction in longest diameter



Same lesion, four ways to measure it

L = longest diameter · W = orthogonal diameter · H = height

NFX-179[3]

Sponsor Nflection Therapeutics

Instrument ruler for L, W and H

Geometry volume = π × (½L)² × H (cylinder)

Response criteria (Ph2b) ≥50% volume reduction in ≥50% of measured lesions



PAS-004[4]

Instrument digital calipers, triplicate

Geometry surface area = π/4 × L × W (ellipse) and longest diameter (L)

Volume extrapolated from area change as a half-ellipsoid



PAS-004-103 reports measured surface area (L × W) as the primary cNF measure; the arithmetic conversion to volume, and its limits, are shown on the preceding slide.

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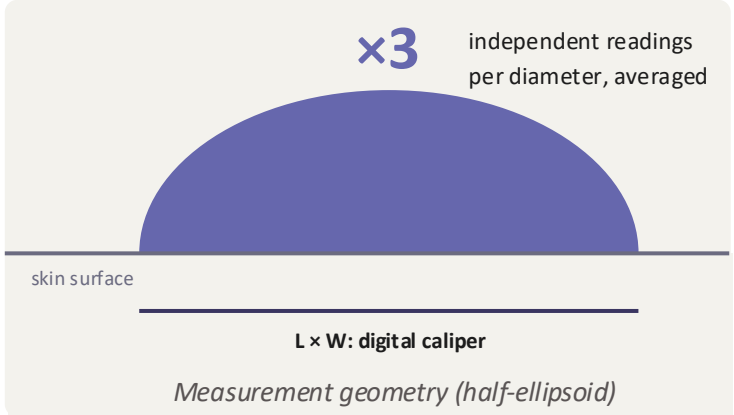
1 Gross et al., JAMA Dermatol 2025 · 2 Romo et al., CTF Conference 2026 · 3 Sarin et al., Sci Adv 2024 · 4 Brown et al., European Neurofibromatosis Conference 2026

Measuring cNF and target lesions at baseline

The study reports length × width (surface area); with isotropic shrinkage the surface area and volume map predictably

Area = π/4 × L × W



Measurement geometry (half-ellipsoid)

CONVERSION TABLE

Surface-area reduction (L × W)	Estimated volume reduction
10%	14.6%
20%	28.4%
30%	41.4%
37%	50.0%
40%	53.5%
50%	64.6%
60%	74.7%
70%	83.6%
80%	91.1%
90%	96.8%

Caution: isotropic shrinkage is a simplifying assumption. Lesions may regress anisotropically (for example flattening disproportionately in height), so true volume change could be larger or smaller than estimated. The conversion is arithmetic, not a measured result.

TARGET cNF LESIONS PER PARTICIPANT

Participant	401-001	401-002	401-003	401-005	402-001	501-001	402-002	502-001	401-007	105-001	401-006	501-003	105-002	501-004	502-002	Total
Dose (mg)	4	4	4	8	8	8	12	12	15	18	18	18	24	24	24	**n = 15**
Target cNF (n)	**7**	**7**	**5**	**5**	**3**	**4**	**5**	**1**	**6**	**6**	**5**	**7**	**6**	**3**	**1**	**71**

Target cNF = lesions with a baseline and at least one post-baseline digital-caliper measurement. Participants 501-002, 501-005, 501-006 and 105-003 had no target cNF and are followed for PN only.

Demographics and time on treatment

DISPOSITION

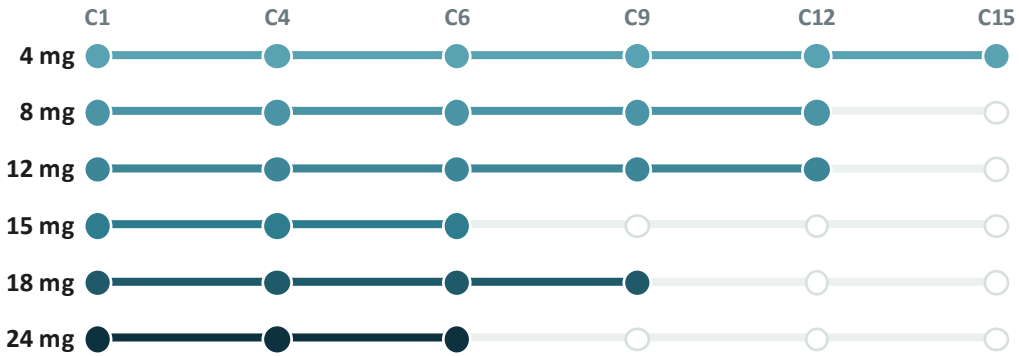
19
enrolled
1 discontinued · sponsor decision due to non-compliance

15
evaluable for cNF
≥1 post-baseline visit

71
target lesions
at baseline

FOLLOW-UP DIFFERS BY COHORT

Treatment cycles reached by at least one participant in the cohort, 07 Oct 2026 cut



BASELINE CHARACTERISTICS — PN POPULATION (N = 19)

Characteristic	PN, N = 19
Age, years, mean (SD)	36.4 (13.0)
Sex, female / male, n	9 / 10
Asian, n (%)	9 (47.4)
White, n (%)	9 (47.4)
Black or African American, n (%)	1 (5.3)
BMI, kg/m², mean (SD)	23.7 (3.1)

BASELINE CHARACTERISTICS — cNF POPULATION (n = 15)

Characteristic	cNF, n = 15
Age, years, mean (SD)	38.5 (13.7)
Sex, female / male, n	6 / 9
Asian, n (%)	6 (40.0)
White, n (%)	8 (53.3)
Black or African American, n (%)	1 (6.7)
BMI, kg/m², mean (SD)	24.2 (3.4)

cNF demographics for the 15 participants with target cNF: the 13 in the interim-analysis efficacy-evaluable population (IA Table 14.1.2, 07 Oct 2026 cut) plus 105-001 and 105-002, whose values are derived from the by-cohort safety-population demographics (Table 14.1.2.1).

PAS-004 pharmacokinetics in NF1 patients show long half-life and low peak-to-trough ratio

PK profile in NF1 participants is consistent with that observed in the PAS-004-102 study in patients with advanced solid tumors

Table 1. Steady-state (Day 28) PK parameters by dose cohort — geometric mean (GeoCV%)

Dose	Cmax (ng/mL)	AUC_{0-24} (ng·h/mL)	Ctau (ng/mL)	Tmax (h)	Cmax / Cmin
4 mg (n=3)	58.1 (35.7)	1,120 (39.8)	37.6 (42.4)	3	1.55
8 mg (n=3)	118 (28.0)	2,290 (24.8)	75.4 (24.2)	3–6	1.56
12 mg (n=3)	215 (32.5)	3,680 (11.9)	109 (20.7)	3–6	1.97
15 mg (n=3)	*PK data still being analyzed*				
18 mg (n=3)	422 (34.3)	8,270 (42.3)	280 (48.8)	3–6	1.51
24 mg (n=3)	452 (25.4)	8,500 (33.2)	268 (39.8)	3–6	1.69

Ctau = concentration at 24 h post-dose · Cmax/Cmin = Cmax ÷ Ctau · 15 mg cohort: bioanalysis still in progress

~40–60 h
long terminal half-life
supports once-daily dosing

3–6 h
predictable Tmax
in every cohort

1.5–2.0
Cmax / Cmin — low peak-to-trough
fluctuation at steady state

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PAS-004 has demonstrated a well tolerated safety profile

Table 1. Overall summary, safety population

Event, n (%)	PAS-004 4–24 mg (N = 19)
Any TEAE related to study drug (TRAE)	**16 (84.2)**
Grade 3 TRAE	2 (10.5)
Grade 4/5 TRAE	0
Serious TRAE	0
Discontinuation due to TRAE	0
Dose interruption due to TRAE	3 (15.8)
Dose modification due to TRAE	not permitted

Of the related adverse events >97% were Grade 1 or 2.
The two Grade 3 TRAE were asymptomatic lab findings: increases in blood CPK, one at 4 mg and one at 8 mg. Each led to a one-week dose interruption, after which the participants continued on study without further problems.

Table 2. Treatment-related adverse events by dose cohort

Related adverse event	Participants	PAS-004 dose cohort (n = 3 each; 18 mg n = 4)											
		4 mg		8 mg		12 mg		15 mg		18 mg		24 mg	
	n (%) of 19	All	G≥3	All	G≥3	All	G≥3	All	G≥3	All	G≥3	All	G≥3
Any related adverse event	**16 (84.2)**												
Dermatitis acneiform	11 (57.9)	1	—	1	—	1	—	2	—	3	—	3	—
Blood CPK increased	5 (26.3)	2	1	2	1	1	—	—	—	—	—	—	—
Diarrhoea	2 (10.5)	—	—	1	—	—	—	—	—	1	—	—	—
Nausea	2 (10.5)	—	—	1	—	—	—	—	—	1	—	—	—
Fatigue	2 (10.5)	—	—	1	—	1	—	—	—	—	—	—	—
Oedema peripheral	3 (15.8)	—	—	—	—	1	—	—	—	—	—	2	—
Neutrophil count decreased	2 (10.5)	—	—	1	—	—	—	—	—	1	—	—	—
Platelet count decreased	2 (10.5)	—	—	—	—	—	—	—	—	1	—	1	—
Constipation	2 (10.5)	—	—	—	—	—	—	—	—	1	—	1	—
Paronychia	2 (10.5)	—	—	1	—	—	—	—	—	—	—	1	—
Pruritus	2 (10.5)	—	—	—	—	—	—	—	—	—	—	2	—
Stomatitis	2 (10.5)	—	—	—	—	—	—	1	—	—	—	1	—

Preferred terms reported by two or more participants are shown. Safety population N = 19 (one 18 mg participant discontinued by Sponsor decision due to poor compliance).

No reported AEs in LVEF, retinopathy or AE related discontinuations:

0%
LVEF reduction (AEs)

0%
retinopathy

0
discontinuations for a related AE

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Study PAS-004-103 · safety population N = 19 · clinical data cut-off 15 Sep 2026

Treatment-related adverse events, 4–12 mg

Table 1. Treatment-related adverse events in the 4, 8 and 12 mg cohorts — the dose range taken forward into PAS-004-201 (IND open)

Related adverse event	Participants	PAS-004 dose cohort (n = 3 each)					
		4 mg		8 mg		12 mg	
	n (%) of 9	All	G≥3	All	G≥3	All	G≥3
Dermatitis acneiform	3 (33.3)	1	—	1	—	1	—
Blood CPK increased	5 (55.6)	2	1	2	1	1	—
Fatigue	2 (22.2)	—	—	1	—	1	—
Diarrhoea	1 (11.1)	—	—	1	—	—	—
Nausea	1 (11.1)	—	—	1	—	—	—
Oedema peripheral	1 (11.1)	—	—	—	—	1	—
Neutrophil count decreased	1 (11.1)	—	—	1	—	—	—
Paronychia	1 (11.1)	—	—	1	—	—	—

Preferred terms reported by two or more participants across the whole study are shown. The two Grade 3 treatment-related events in the study were increases in blood CPK (one at 4 mg, one at 8 mg); both resolved after a one-week dose interruption and the participants continued on study. Under CTCAE v6 — planned to be used in the 201 study — a CPK increase that is not clinically relevant is no longer classified as an adverse event. No related event led to discontinuation.

33%
dermatitis acneiform

11%
diarrhoea (GI toxicity)
all Grade 1

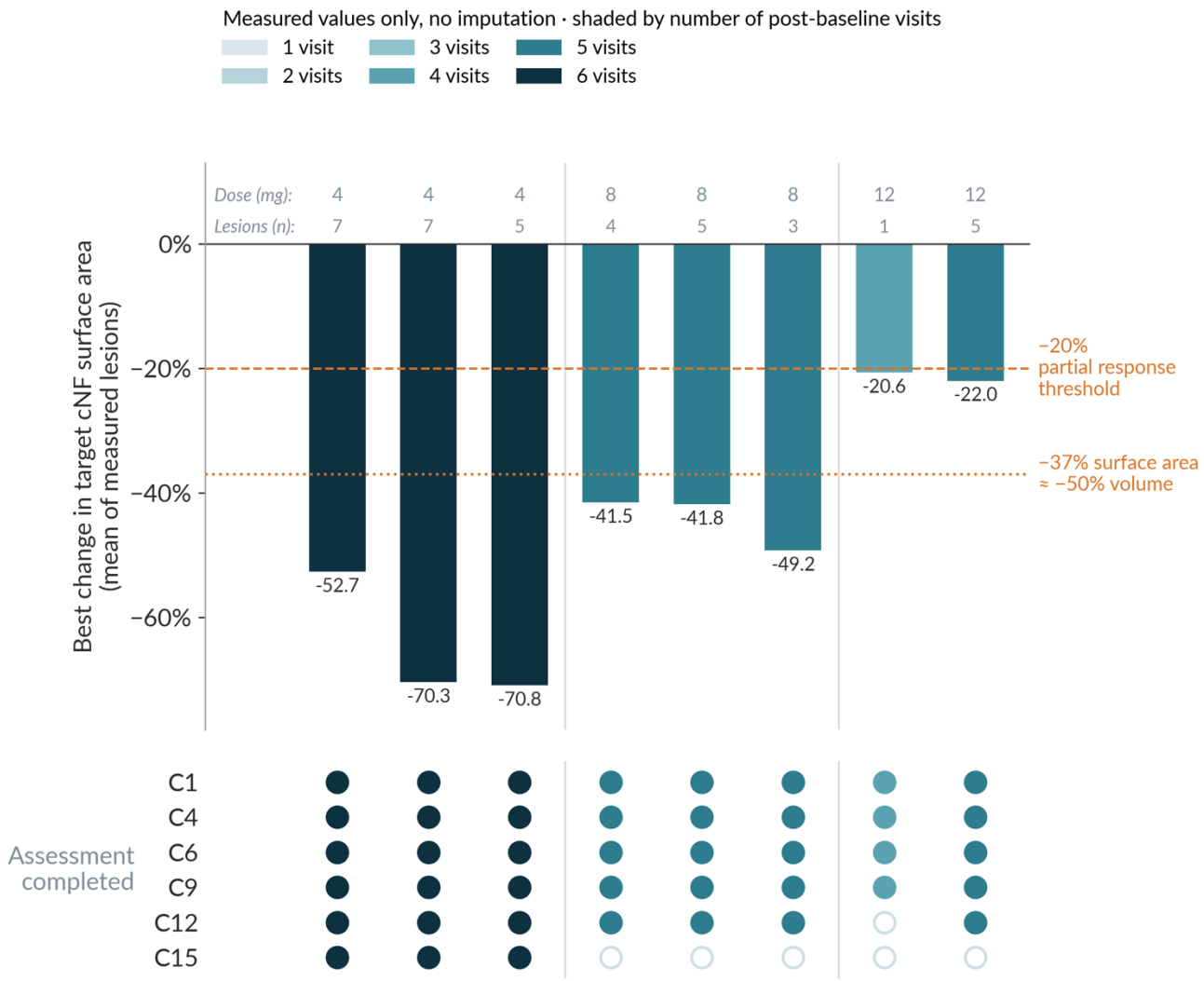
0%
LVEF reduction
(AEs)

0%
retinopathy

0
discontinuations
for a related AE

0
serious TRAEs

cNF surface area, best mean change per participant in the 4–12 mg range



4–12 mg · PAS-004-201 dose range

8 participants · 37 target lesions · best post-baseline value

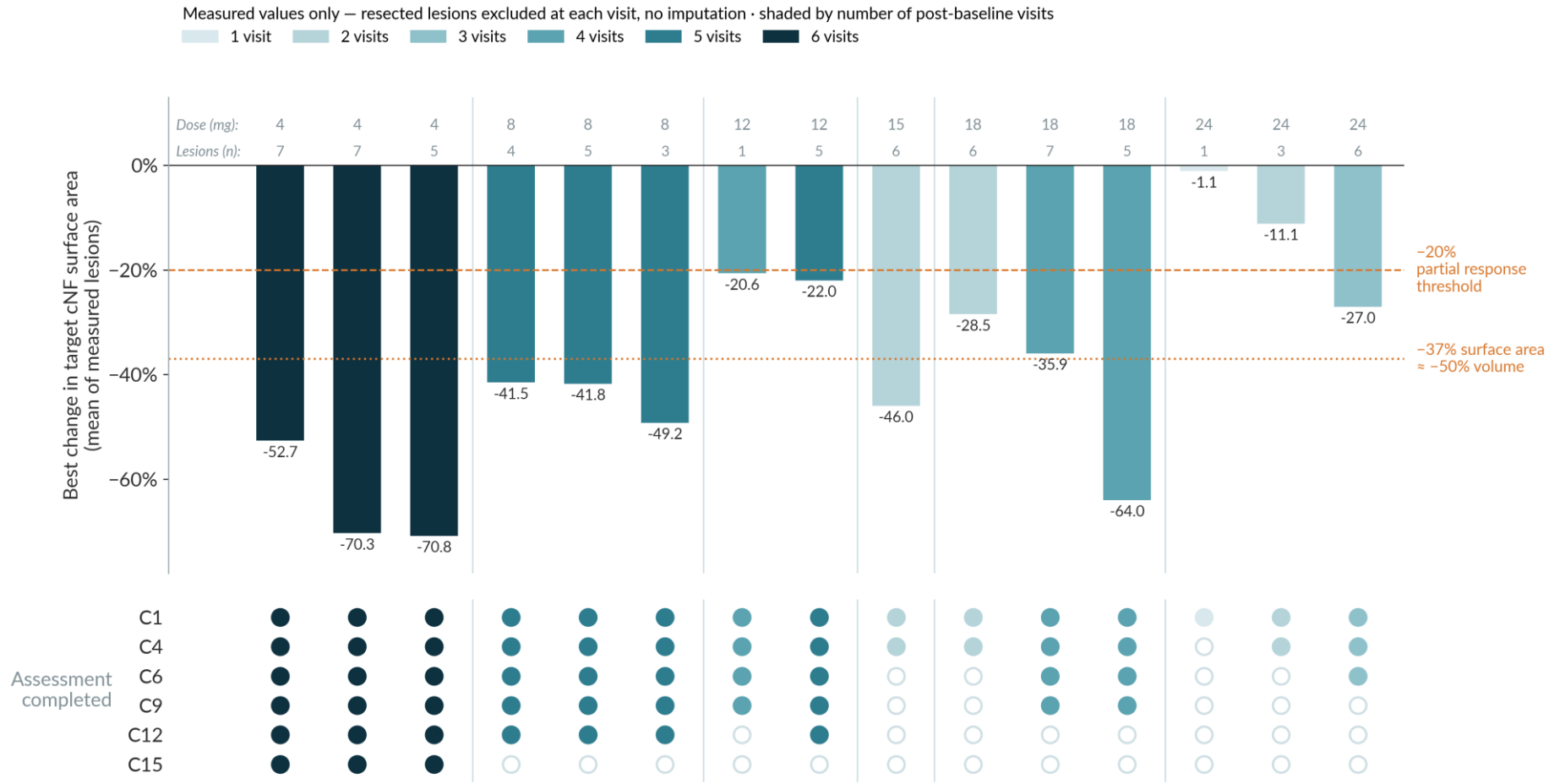
8 of 8 (100%)
participants with a >20% reduction in cNF surface area

6 of 8 (75%)
participants with a ≥37% reduction in surface area (≈ 50% volume)
median best change across the 8 participants: 46% reduction

29 of 37 (78%)
target lesions shrank ≥37% in surface area ≈ 50% volume · 34 of 37 ≥20%

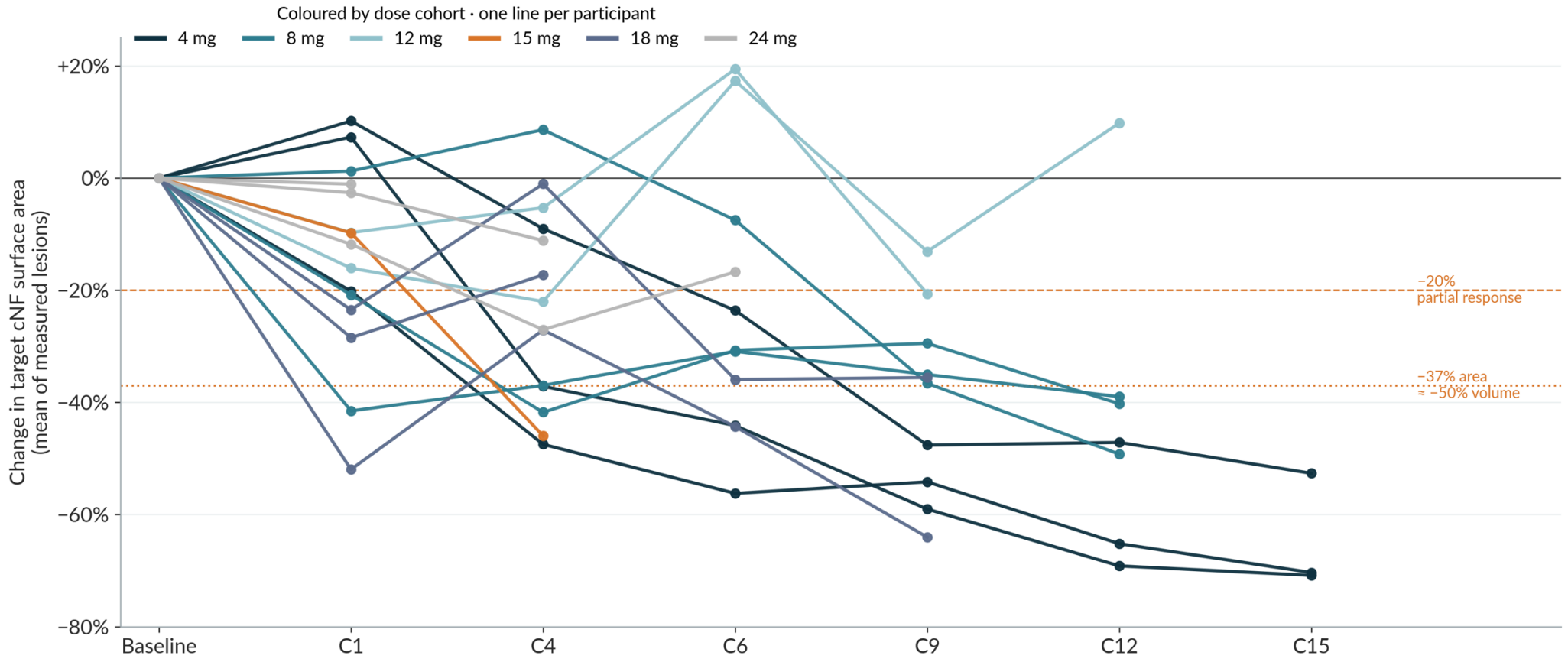
Data cut-off: 07 Oct 2026

cNF surface area, best mean change per participant
Profound Activity, Even at Lowest Doses Tested



Data cut-off: 07 Oct 2026

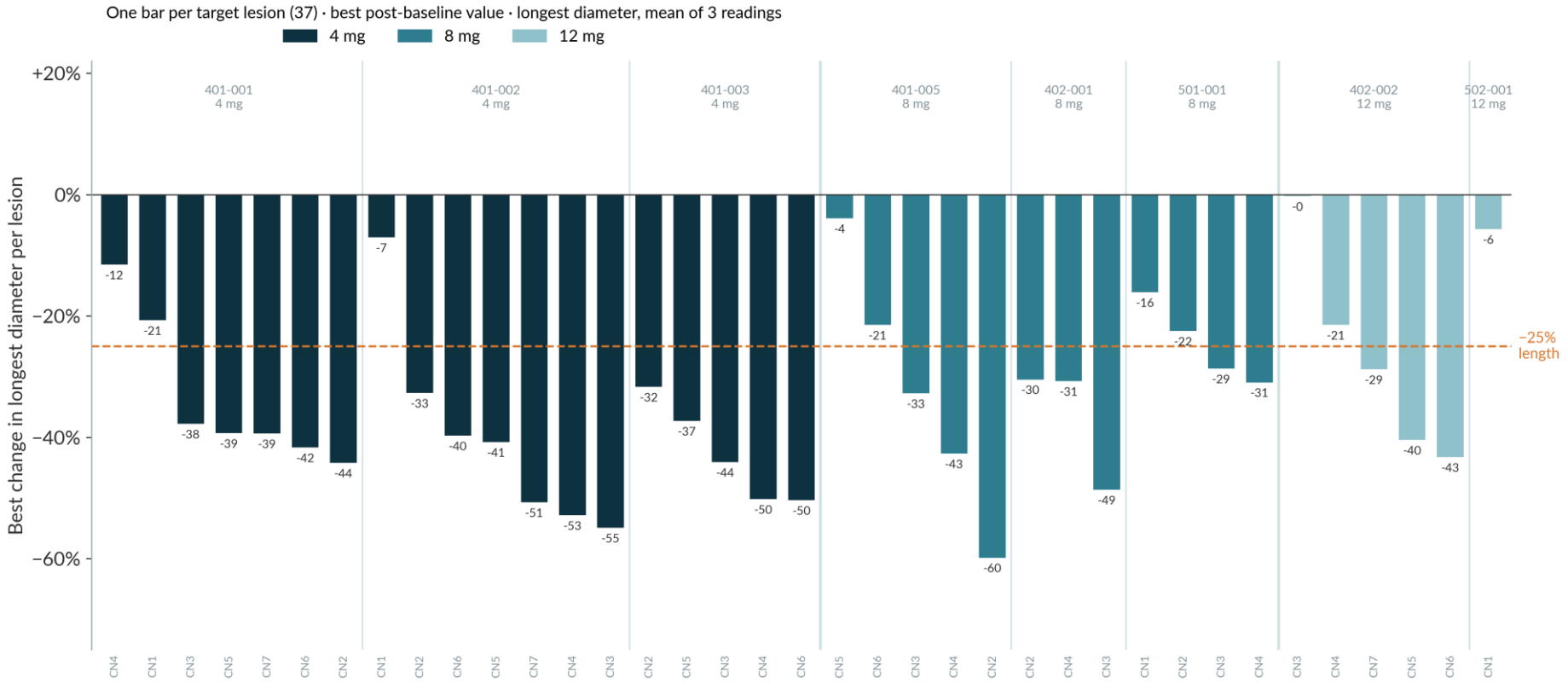
cNF Average Surface Area Change per Participant Demonstrates Continued Improvement Over Time



Data cut-off: 07 Oct 2026

cNF longest diameter per lesion, 4–12 mg range

27 of 37 target lesions (73%) achieved a ≥25% reduction in longest diameter · 31 of 37 (84%) ≥20%



5 of 8 (63%)
participants with a ≥25% reduction in mean target longest diameter

27 of 37 (73%)
target lesions achieved a ≥25% reduction in longest diameter (31 of 37 ≥20%)

34% reduction
median best change in longest diameter across the 8 participants

One bar per target lesion (37, 4–12 mg cohorts) · best post-baseline reduction in longest diameter · 27/37 (73%) ≥25% reduction

Data cut-off: 07 Oct 2026

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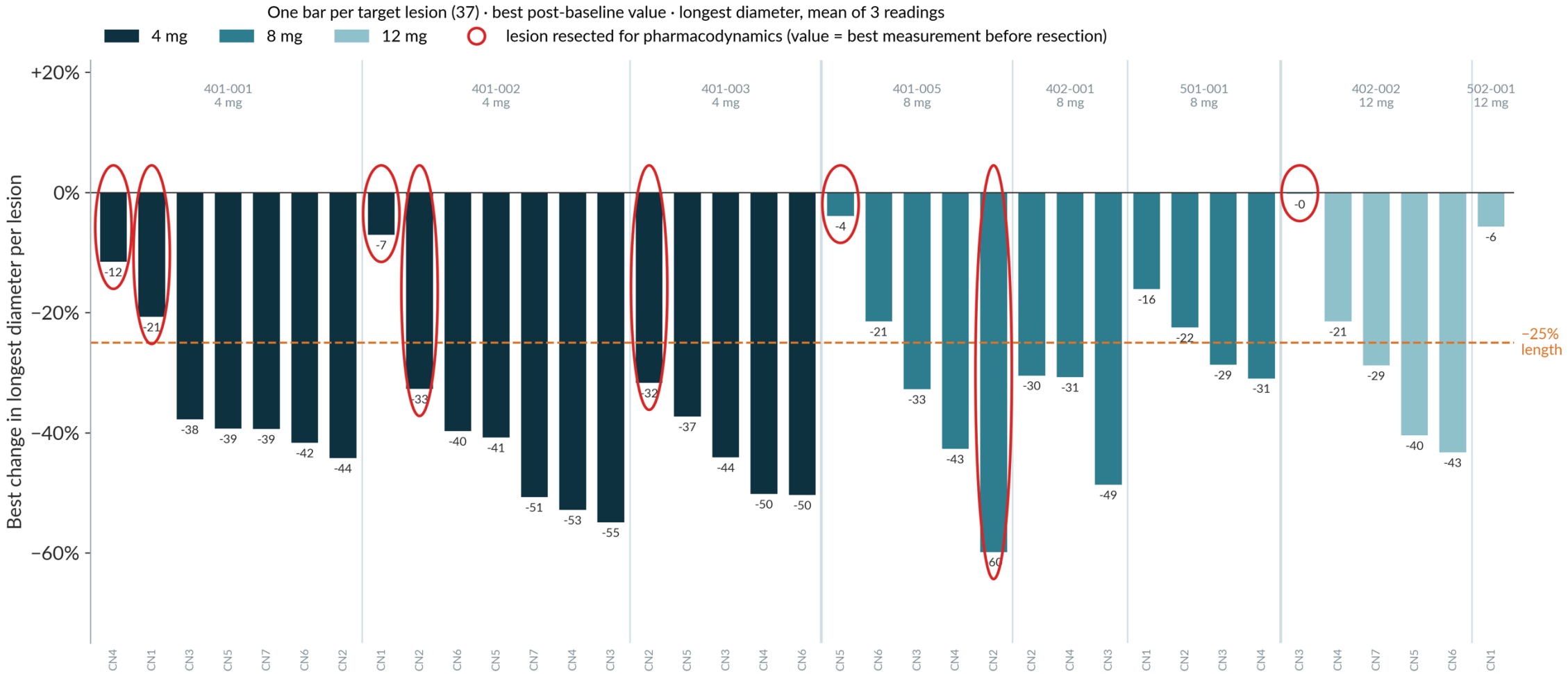
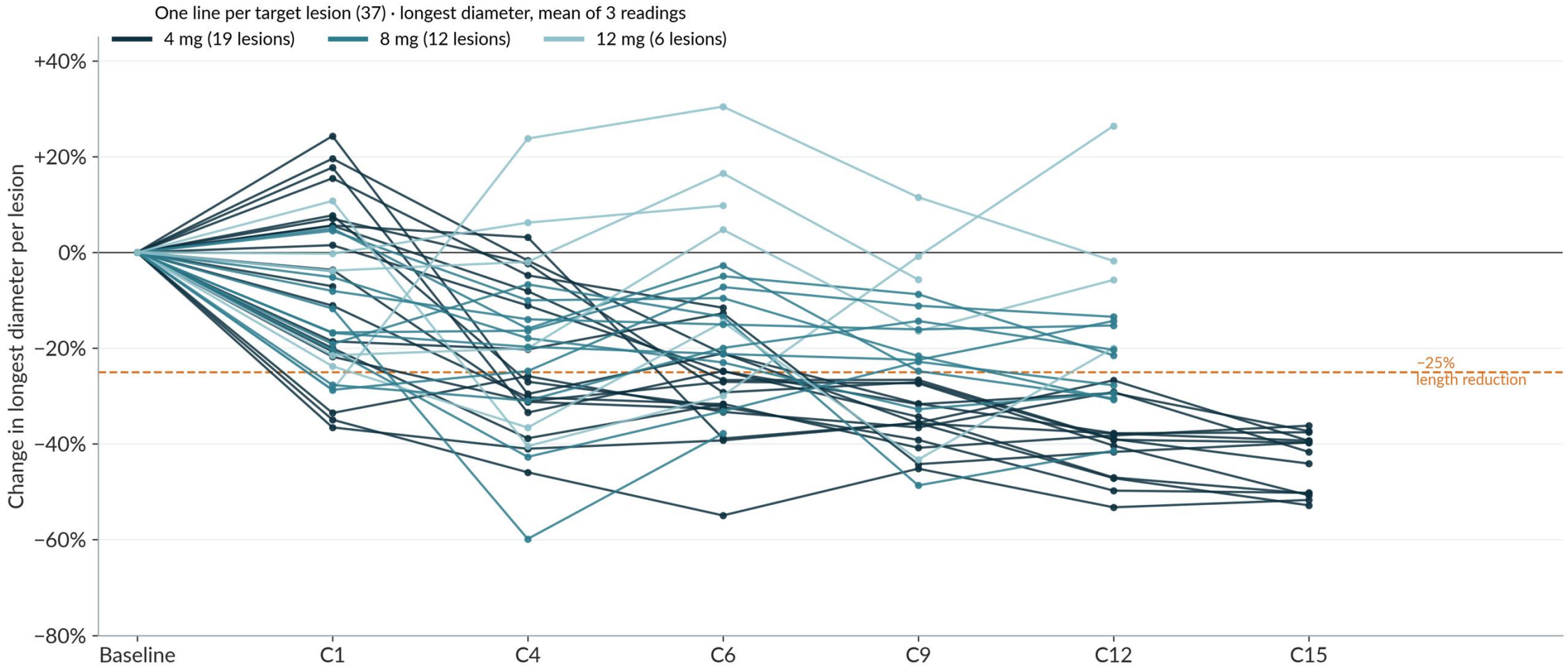
Longest diameter per lesion, 4–12 mg, resected lesions marked

Red circles: 8 of 37 lesions resected for pharmacodynamics · 24 of 29 never-resected lesions (83%) reached ≥25%



Longest diameter per lesion over time, 4–12 mg



One line per target lesion (37, 4–12 mg cohorts) · change in longest diameter at each visit, measured values only

Data cut-off: 07 Oct 2026

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PAS-004 Induces cNF Reductions Across Multiple Response Criteria

PAS-004-103 cNF response analysis · measured surface area, inferred volume and measured longest diameter, lesion and participant level

Table 1. Surface area, measured — best value per lesion

Measured surface area (length × width)	Result
Lesions with ≥20% area reduction	**60 / 71 (85%)**
Lesions with ≥37% area reduction	**48 / 71 (68%)**
Participants with ≥50% of lesions reduced ≥20%	**14 / 15 (93%)**
Participants with ≥50% of lesions reduced ≥37%	**10 / 15 (67%)**

Resected lesions excluded, no imputation; best value per lesion, % change rounded to the nearest whole percent before applying thresholds. A 37% area reduction corresponds to ~50% volume.

Table 2. Volume, inferred from area (isotropic)

Inferred volume (isotropic conversion)	Result
Lesions with ≥30% volume reduction	**59 / 71 (83%)**
Lesions with ≥50% volume reduction	**48 / 71 (68%)**
Participants with ≥50% of lesions reduced ≥30%	**14 / 15 (93%)**
Participants with ≥50% of lesions reduced ≥50%	**10 / 15 (67%)**

Thresholds correspond to those planned for Study PAS-004-201. Lesion-level volume is inferred from area, not measured.

Table 3. Longest diameter, 4–12 mg range (PAS-004-201 doses)

Longest diameter, 4–12 mg (n = 8)	Result
Lesions with ≥20% reduction	**31 / 37 (84%)**
Lesions with ≥25% reduction	**27 / 37 (73%)**
Participants with ≥25% reduction in mean diameter	**5 / 8 (63%)**
Median best reduction in longest diameter	**34%**

Tables 1–2: all cohorts (15 participants, 71 lesions). Table 3: 4–12 mg cohorts only, the PAS-004-201 dose range; 25% diameter ≈ 37% area ≈ 50% volume.

85%
of target lesions shrank by ≥20% measured surface area, 60 of 71

68%
of target lesions shrank by ≥37% area ≈ 50% volume, 48 of 71

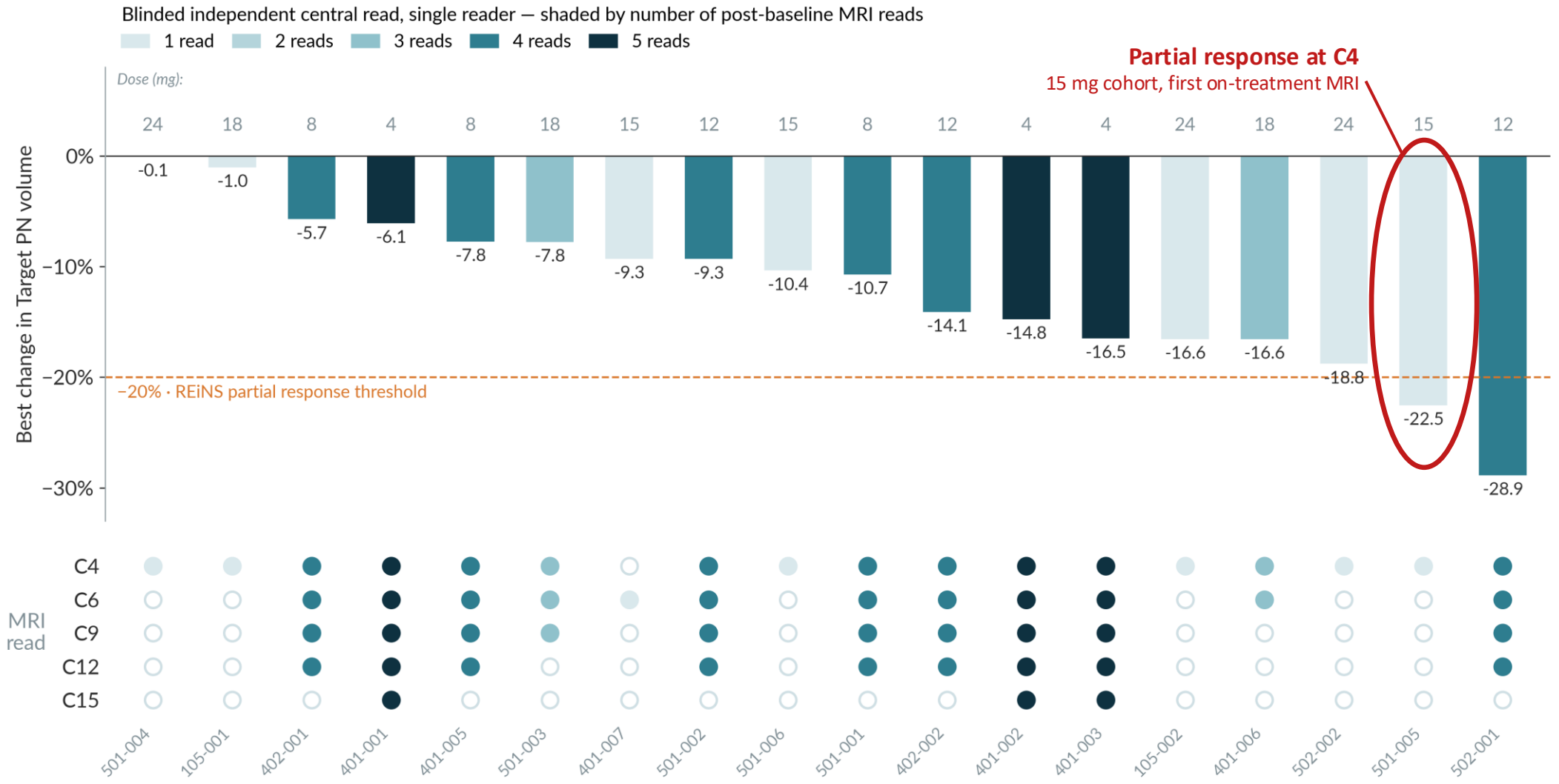
14 / 15
participants with ≥50% of lesions at ≥20% area reduction 10 of 15 met the ≥37% threshold

ON THE VOLUME CONVERSION

Height was not measured, so volume is inferred from area assuming a lesion shrinks at the same rate in all three directions.

Data cut-off: 07 Oct 2026

Change in target PN volume, blinded independent central read



Blinded independent central read, single reader · best post-baseline value per participant · MRI data cut-off 30 Sep 2026

Conclusions

EFFICACY — cNF (CUTANEOUS NEUROFIBROMA)

15/15
participants with a reduction in surface area at best response (71 target lesions)

13/15 (87%)
participants had a >20% reduction in cNF surface area at best response

78%
of target lesions in the 4–12 mg range (study 201 doses) shrank by ≥37% in surface area, ≈50% in volume (29 of 37)

EFFICACY — PN (PLEXIFORM NEUROFIBROMA)

18/18
showed a reduction in Target PN volume at best assessment (blinded independent central read)

2 responders
≥20% PN volume reduction by central read: one at 12 mg and one at 15 mg, the latter at Cycle 4, the first on-treatment MRI

28.9%
greatest centrally measured PN volume reduction (12 mg cohort)

SAFETY

10.5%
GI toxicity (diarrhoea, 2 of 19 participants), all Grade 1; nausea also 2 of 19, Grade 1

Mostly Grade 1 AEs
74% of treatment-related events were Grade 1 and 98% Grade 1–2; two Grade 3 CPK increases, each resolved

0
related serious events or discontinuations for a related adverse event

0%
treatment-related LVEF reduction (cardiac) at any dose

0%
treatment-related retinopathy at any dose

33%
rash rate at the 4–12 mg doses taken into the cNF study

Preliminary evidence of PAS-004 activity in both cNF and PN, with cNF reductions generally deepening during continued treatment and no treatment-related LVEF reductions or retinopathy reported to date. The 4–12 mg range is taken forward into PAS-004-201 (IND open).