

# Long-term Safety and Efficacy of Roflumilast Cream 0.3% in Adult Patients With Chronic Plaque Psoriasis: Results From a 52-Week, Phase 2b Open-Label Study

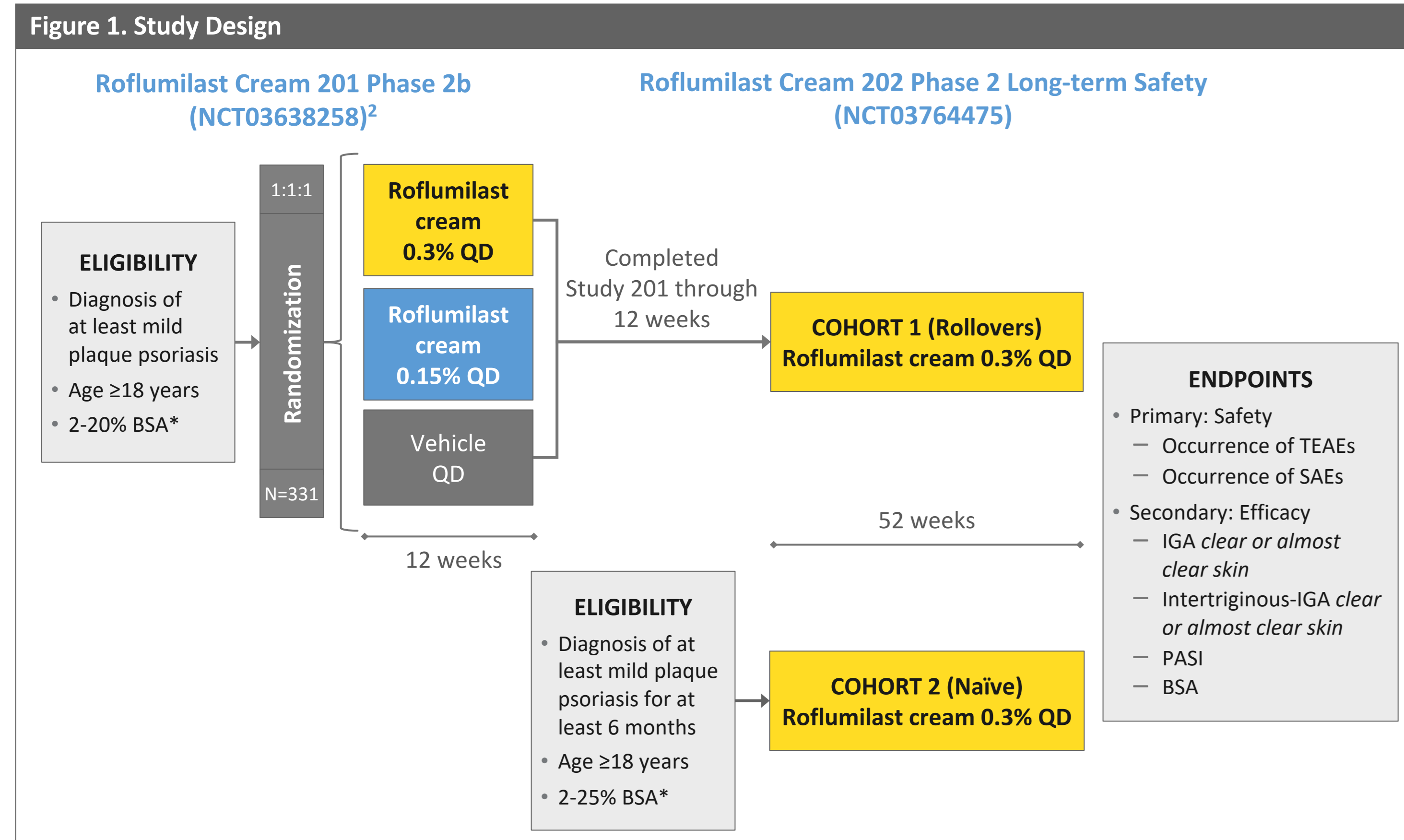
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## INTRODUCTION

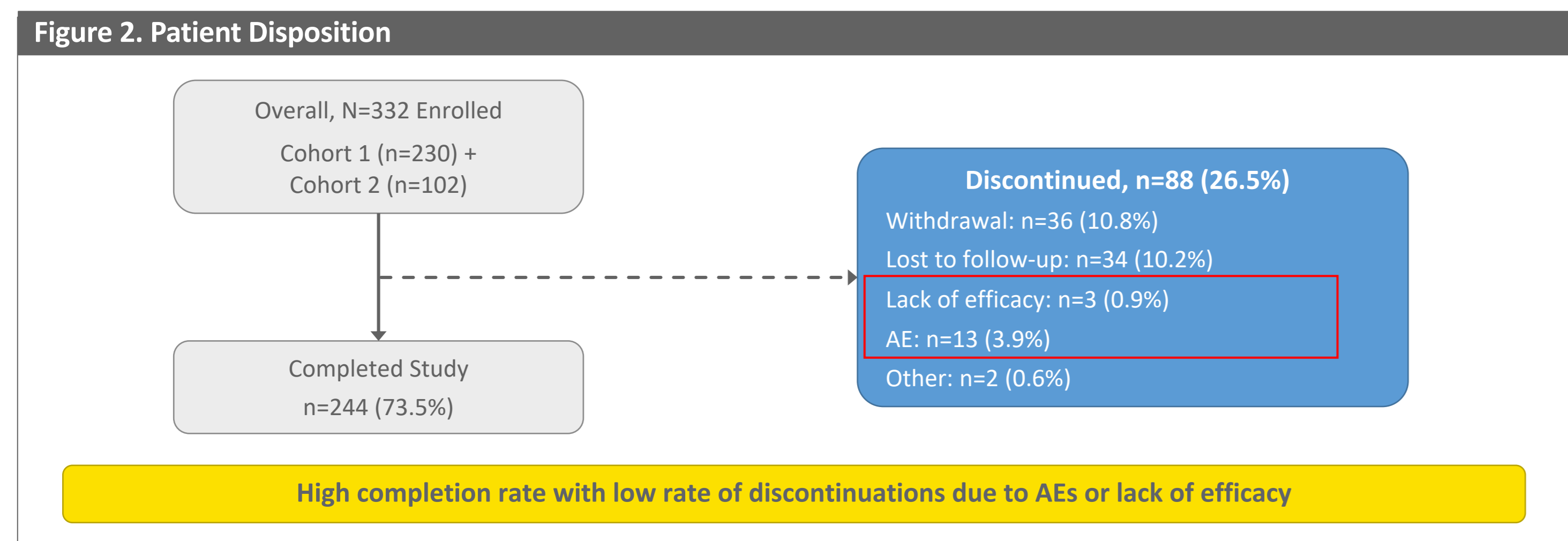
- Topical treatment options for chronic plaque psoriasis lack products that are safe with long-term usage, are well tolerated, and are used as single agents over the entire body
- Roflumilast cream, a phosphodiesterase-4 (PDE-4) inhibitor that is more potent than other PDE-4 inhibitors,<sup>1</sup> is under investigation as a once-daily, nonsteroidal, topical treatment for psoriasis
- In a phase 2b randomized, double-blind, 12-week trial of 331 adults with chronic plaque psoriasis, roflumilast cream once daily was found to be superior to vehicle cream and was well tolerated<sup>2</sup>
- This multicenter, open-label, 52-week study was also conducted to assess long-term safety of roflumilast 0.3% cream in patients with chronic plaque psoriasis

## METHODS



\*Excludes scalp, palms, soles.  
 BSA: body surface area; IGA: Investigator Global Assessment; QD: once daily; PASI: Psoriasis Area Severity Index; SAE: serious adverse event; TEAE: treatment-emergent adverse event.

## RESULTS



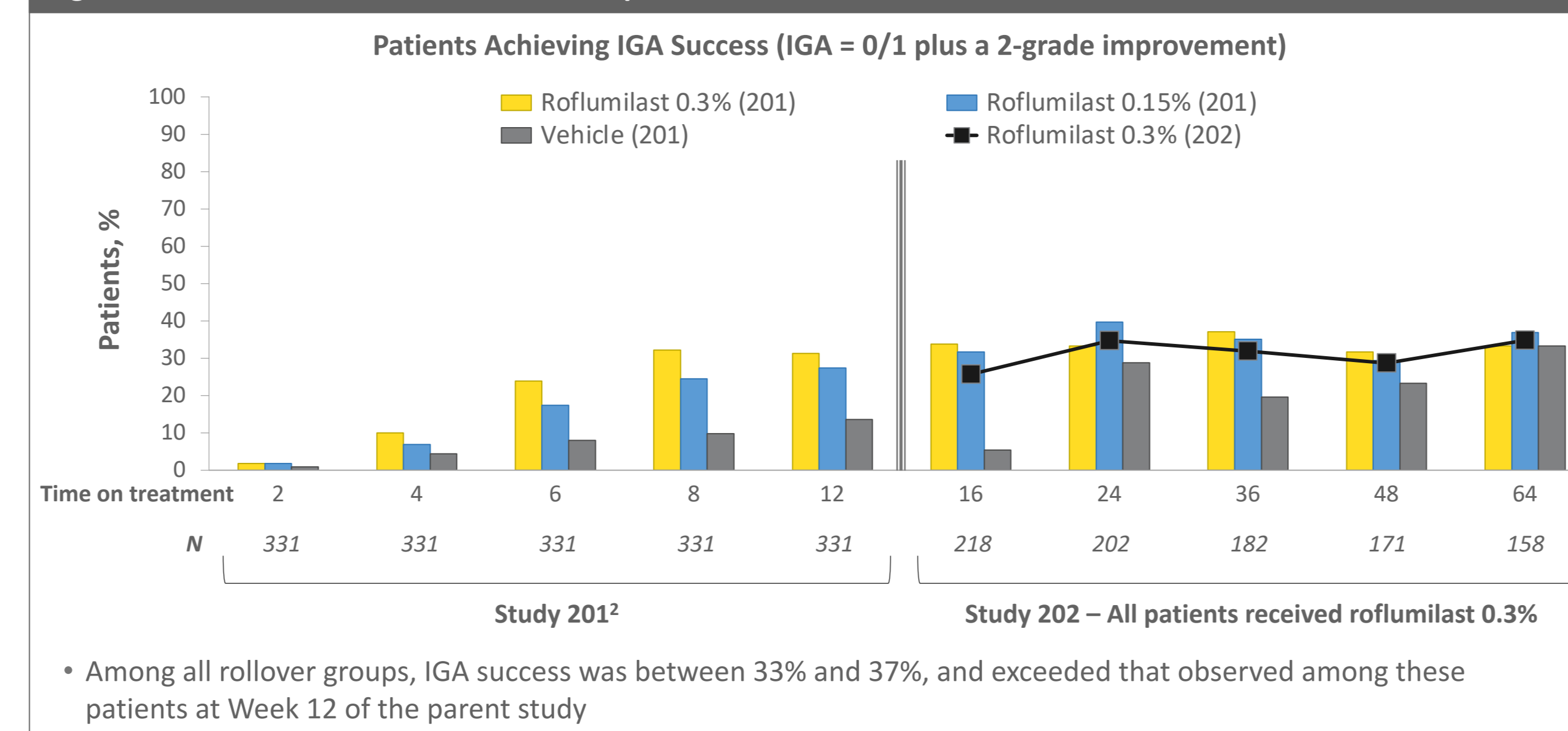
AE: adverse event.

**Table 1. Baseline Disease Characteristics**

	Cohort 1 Total (n=230)	Cohort 2 Total (n=102)	Overall Total (N=332)
BSA, mean %	6.2	6.6	6.3
PASI, mean	7.2	6.8	7.1
IGA score, n (%)			
1 (almost clear)	8 (3.5)	0 (0.0)	8 (2.4)
2 (mild)	51 (22.2)	17 (16.7)	68 (20.5)
3 (moderate)	156 (67.8)	78 (76.5)	234 (70.5)
4 (severe)	15 (6.5)	7 (6.9)	22 (6.6)
Intertriginous Involvement (I-IGA ≥2)			
I-IGA, n (%)			
2 (mild)	19 (8.3)	12 (11.8)	31 (9.3)
3 (moderate)	17 (7.4)	12 (11.8)	29 (8.7)
4 (severe)	2 (0.9)	0 (0.0)	2 (0.6)

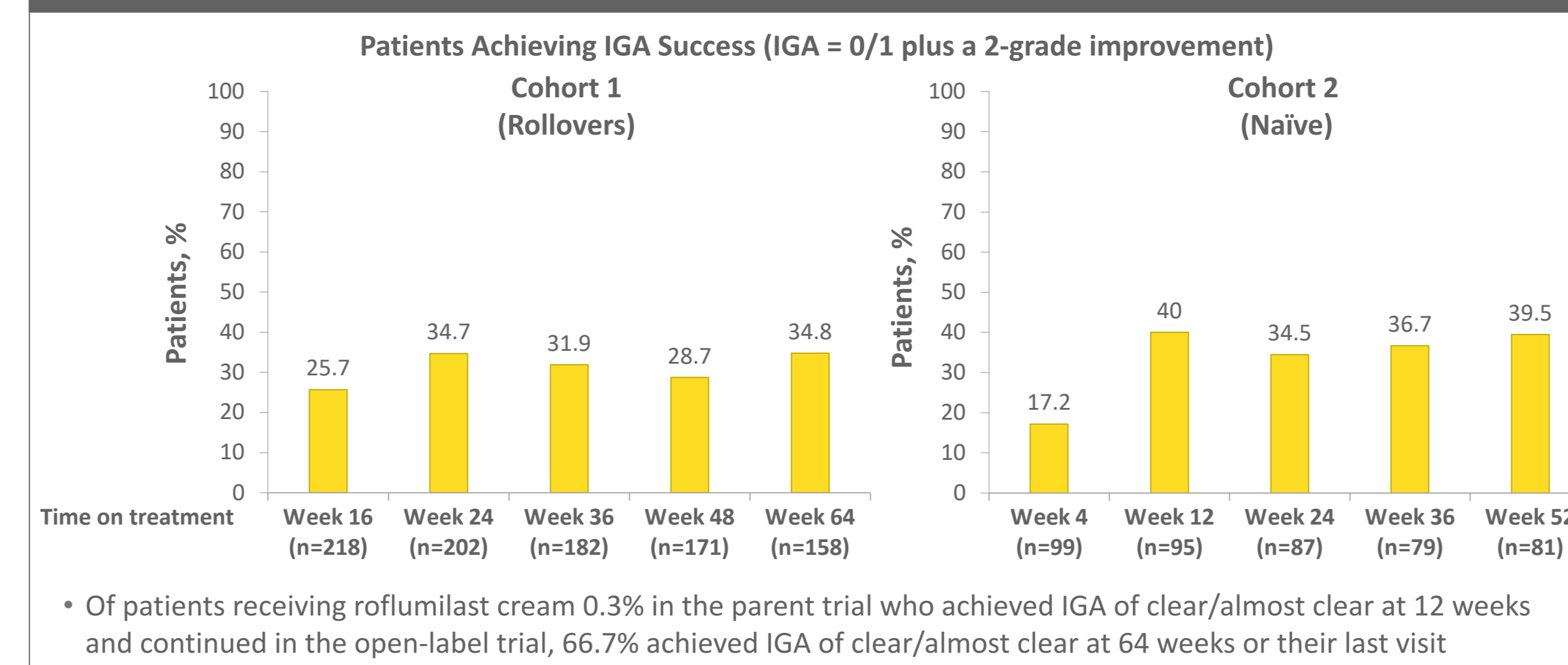
Baseline is defined as the last observation prior to the first dose of roflumilast cream in either the ARQ-151-201 or ARQ-151-202 study.  
 BSA: body surface area; IGA: Investigator Global Assessment; I-IGA: Intertriginous Investigator Global Assessment; PASI: Psoriasis Area and Severity Index.

**Figure 3. Roflumilast Provided Durable Improvement in IGA**



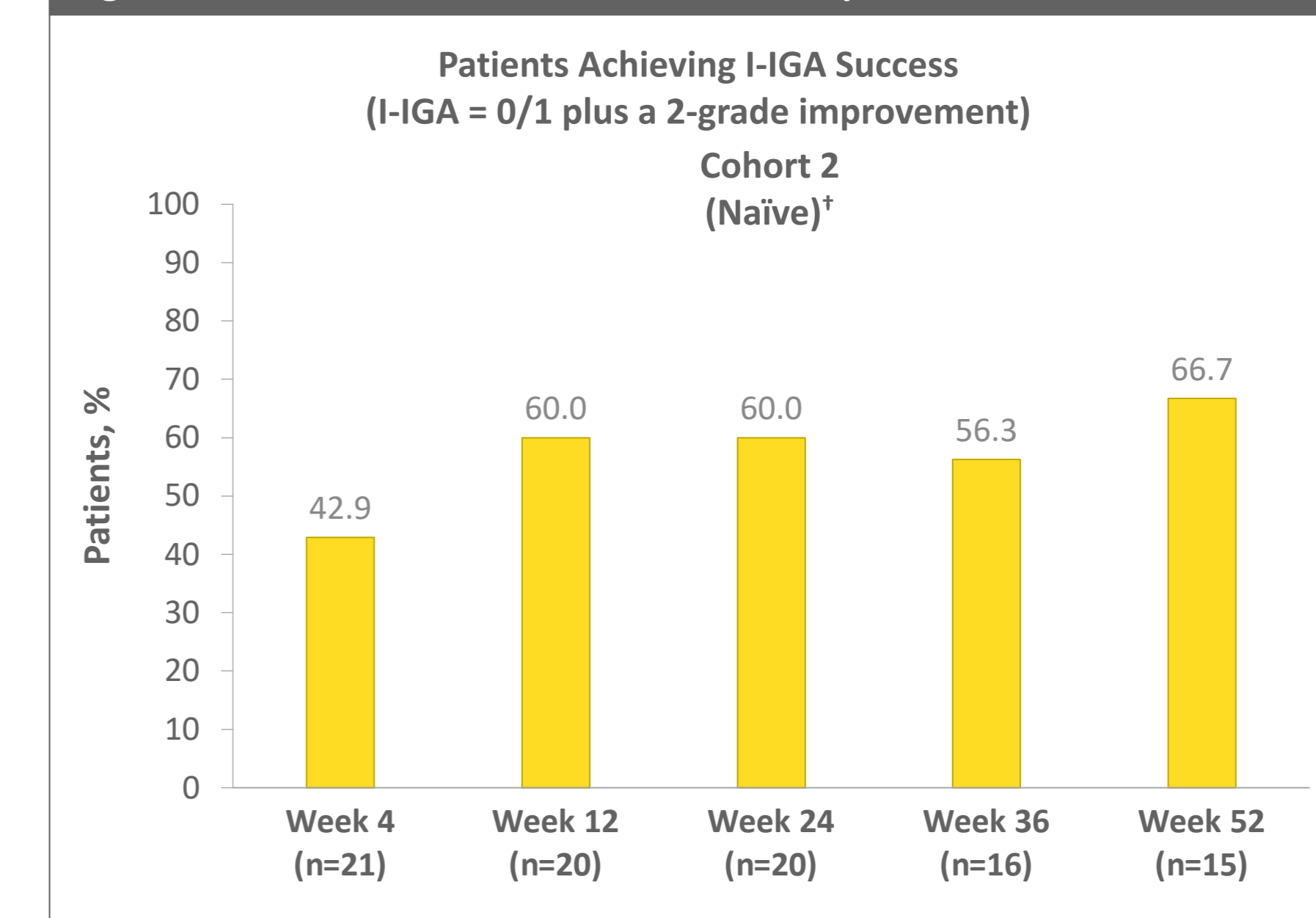
No imputation of missing values. Baseline is defined as the last observation prior to the first dose of ARQ-151 cream in either the ARQ-151-201 or ARQ-151-202 study.  
 IGA: Investigator Global Assessment.

**Figure 4. The Proportion of Patients With IGA status of 'Clear' or 'Almost Clear' With Roflumilast Was Consistent Over Time**



IGA: Investigator Global Assessment.

**Figure 5. Roflumilast Provided Consistent Improvement of I-IGA<sup>†</sup>**



<sup>†</sup>Cohort 1 not shown because I-IGA added as study amendment and numbers of patients evaluated are very small at each timepoint; <sup>‡</sup>Collected post-baseline for patients with a severity of at least mild.  
 I-IGA: Intertriginous-area Investigator Global Assessment.

- 94% of AEs were rated mild or moderate
- 97% of AEs were unrelated or unlikely to be related to treatment as determined by the investigator
- Rates of gastrointestinal and psychiatric AEs were low
- ≥97% of patients had no evidence of irritation per physician assessment at each visit

**Table 2. Summary of AEs (Safety Population)**

TEAE, n (%)	Cohort 1 Total (n=230)	Cohort 2 Total (n=102)	Overall Total (N=332)
Patients with any TEAE	104 (45.2)	60 (58.8)	164 (49.4)
Patients with any treatment-related TEAE	7 (3.0)	5 (4.9)	12 (3.6)
Patients with any SAE	10 (4.3)	2 (2.0)	12 (3.6)
- Any treatment-related SAE	0 (0)	0 (0)	0 (0)
Patients who discontinued study drug due to AE	11 (4.8)	2 (2.0)	13 (3.9)

TEAE defined as event with an onset on or after the date of the first study drug application in ARQ-151-202 study.  
 AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event.

**Table 3. Most Common AEs (>2% Overall)**

TEAE, n (%)	Cohort 1 Total (n=230)	Cohort 2 Total (n=102)	Overall Total (N=332)
Upper respiratory tract infection/viral URTI	14 (6.1)	8 (7.8)	22 (6.6)
Urinary tract infection	9 (3.9)	4 (3.9)	13 (3.9)
Nasopharyngitis	8 (3.5)	5 (4.9)	13 (3.9)
Sinusitis/chronic sinusitis	3 (1.3)	6 (5.9)	9 (2.7)
Hypertension/essential hypertension	8 (3.5)	1 (1.0)	9 (2.7)
Arthralgia	7 (3.0)	1 (1.0)	8 (2.4)
Back pain	5 (2.2)	2 (2.0)	7 (2.1)
Cough	4 (1.7)	3 (2.9)	7 (2.1)

AE: adverse event; TEAE: treatment-emergent adverse event; URTI: upper respiratory tract infection.

## CONCLUSIONS

- Patients with chronic plaque psoriasis need topical treatments that provide effective control of psoriasis with low incidence of side effects that can be used for long-term treatment
- In this phase 2 long-term safety study, roflumilast cream, an investigational, once-daily, nonsteroidal topical PDE-4 inhibitor, was well-tolerated with no new safety signals
  - Rates of discontinuations due to AEs and lack of efficacy were low
- Durable efficacy was observed and the effect was maintained through 52 weeks of treatment in this long-term safety study and up to 64 weeks including the phase 2b study
  - Similar durability of effect was observed in patients with intertriginous area involvement
- Once-daily roflumilast cream is a promising novel therapy for treating plaque psoriasis

## REFERENCES

- Dong C, et al. *J Pharmacol Exp Ther* 2016;358:413-422.
- Lebwohl MG, et al. *N Engl J Med* 2020;383:229-239.

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