High Efficacy of 1% Benvitimod Cream in Pediatric Patients with Atopic Dermatitis: A Post-hoc Analysis of a Phase Ⅲ Trial

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Learning Objectives : Describe the efficacy and safety of benvitimod 1% cream in pediatric AD.

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Conflict of Interest Disclosure

Jianzhong Zhang is the principal investigator of this study. He has served as an advisor for several pharmaceutical companies.

Genhui Chen is the staff of Thederma Shanghai Co., Ltd.

Lin Ma participated in this study and declared no conflict of interest.

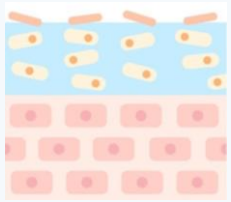
Pediatric AD: High Prevalence and Unmet Needs

High Prevalence Of Pediatric in China and all over world

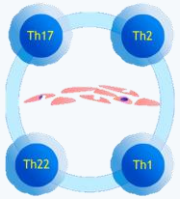
Global:
~72.4 million patients with pediatric AD

China:
12.9% of children suffering AD

Distinct Pathophysiological Features



Immature Skin Barrier:
Thinner and more sensitive



Immune response patterns are not identical to adults

Limitations of Existing Treatment

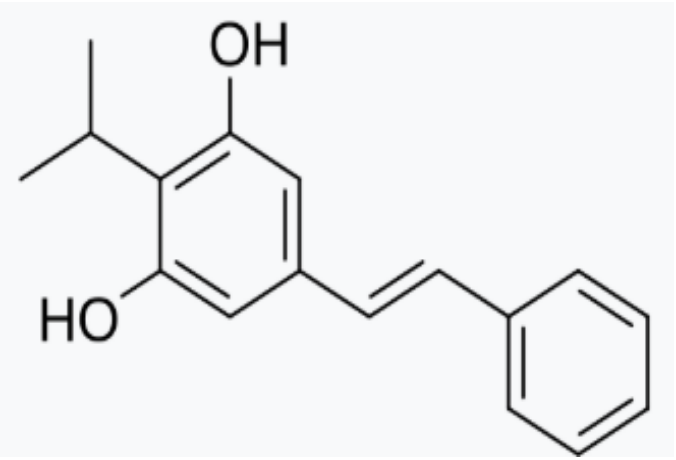
- The side-effects of steroid prevent it from long-term use in children
- The efficacy of available options is often insufficient or not well-sustained

Jin, Ling et al. Annals of allergy, asthma & immunology : official publication of the American College of Allergy, Asthma, & Immunology vol. 134,5 (2025): 603-609.e6.

Benvitimod: an Aryl Hydrocarbon Receptor (AhR) Modulators

Benvitimod is a novel, **non-steroidal** Aryl Hydrocarbon Receptor (AhR) modulator.

It has been shown that benvitimod could inhibit skin type two inflammation and up-regulate skin barrier molecules



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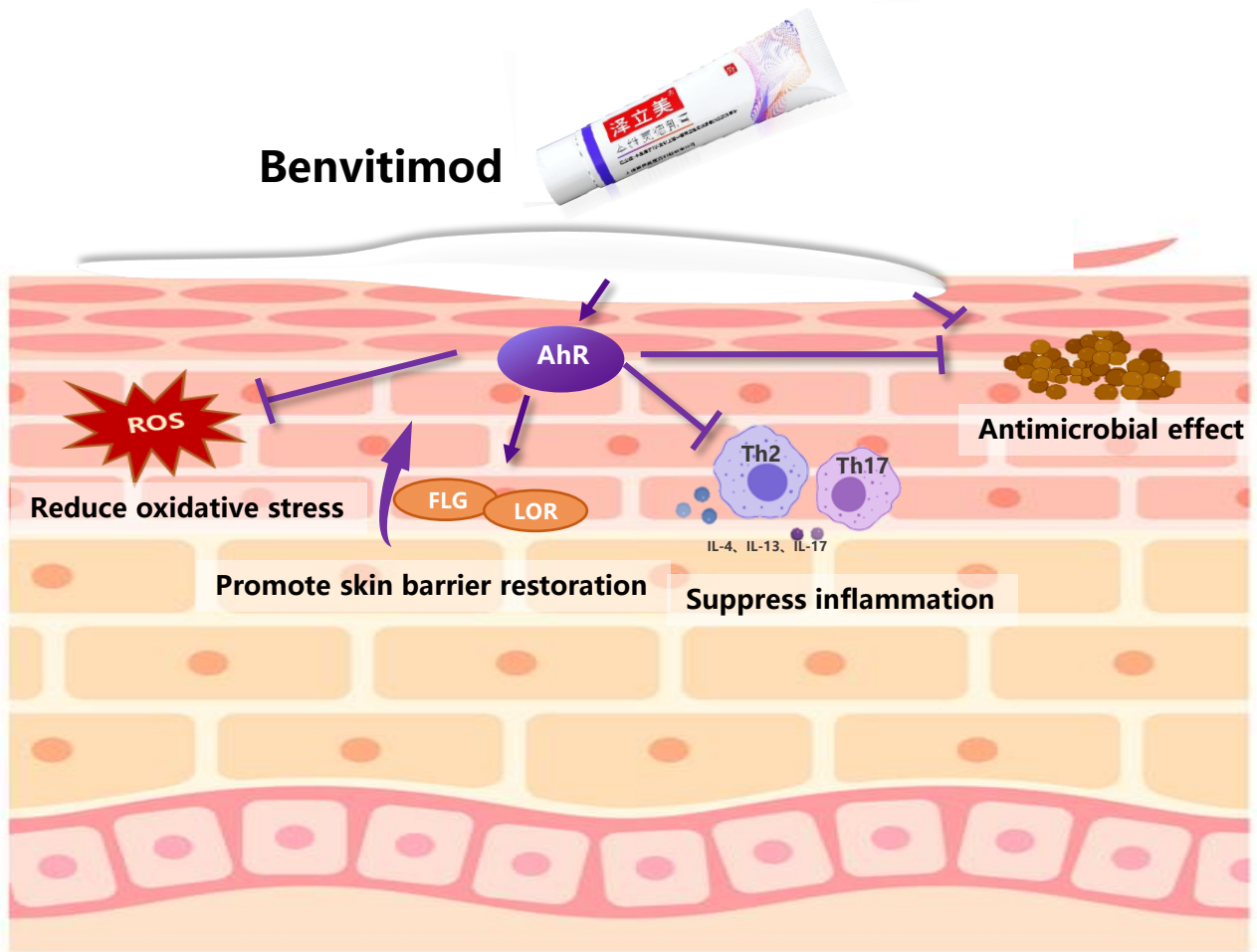
Benvitimod: Possible Mechanism of Action for Treatment of AD



1.Inflammation Inhibition

Inhibits Th17 differentiation and IL-17 production； Promotes Treg differentiation and function； Indirectly suppresses the Type 2 inflammatory IL-4/IL-13 axis by inhibiting STAT6 activation.

2.Skin Barrier Repairment

Directly upregulates the expression of key skin barrier proteins, including Filaggrin (FLG), Loricrin (LOR), Involucrin (IVL), and tight junction (TJ) proteins.

3. Oxidative Stress Protection

Activates the Nrf2 antioxidant pathway, neutralizes reactive oxygen species (ROS), and enhances resistance against oxidative stress.

4.Skin Microbiome Equillibrium

Directly inhibits the proliferation of pathogenic bacteria (e.g., Staphylococcus aureus)； Promotes the expression of antimicrobial peptides (AMPs)； Helps restore skin microbiota balance.

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2.Furue M, et al. Int J Mol Sci. 2019;20(21):5424.
3.Silverberg, Jonathan I et al. J Allergy Clin Immunol. 2024 Jul.
4.Park, Hyun Bong et al. Angew Chem Int Ed Engl. 2020 May 11;59(20):7871-7880.

Study Design

A double-blinded, placebo-controlled, multicentered Phase 3 clinical trial in China evaluating the efficacy and safety of benvitimod in patients with atopic dermatitis .

Aim of the Study

- To evaluate the efficacy and safety of benvitimod in the treatment of atopic dermatitis in patients aged 2 years and above.
- To further analyze the efficacy of benvitimod in pediatric patients subgroup.

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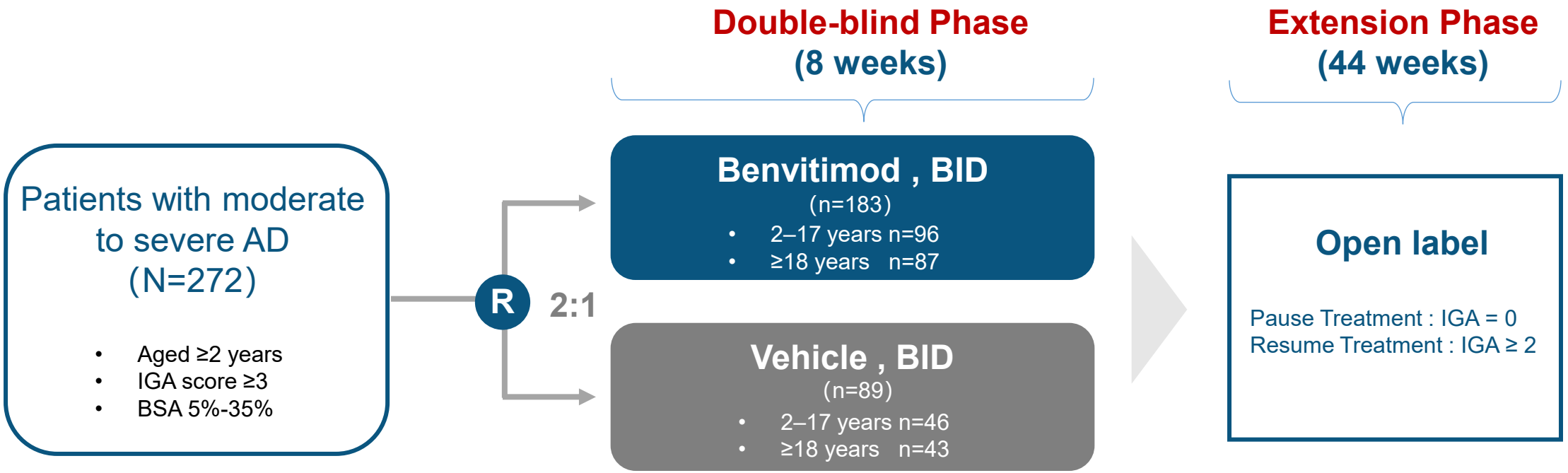


BID :twice daily

Baseline Demographic and Clinical Characteristics

Predominantly Pediatric Population (>50% Participants Aged 2–17)

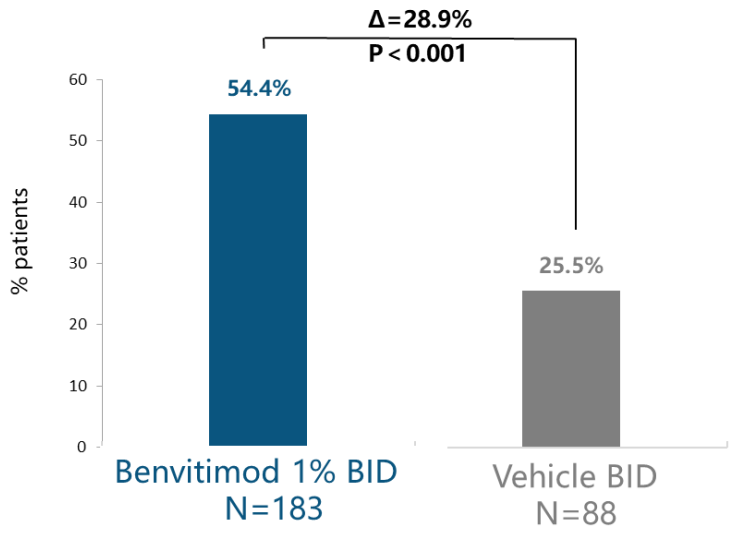
Characteristics	Benvitimod (n = 183)	Vehicle (n = 89)
Age (years), mean ± SD	25.5 ± 20.6	24.9 ± 19.5
Age group, n (%)		
2–11 years	73 (39.9)	35 (39.3)
12–17 years	23 (12.6)	11 (12.4)
≥18 years	87 (47.5)	43 (48.3)
Sex, n (%)		
Male	87 (47.5)	61 (68.5)
Female	96 (52.5)	28 (31.5)

Moderate to Severe AD

Characteristics	Benvitimod (n = 183)	Vehicle (n = 89)
EASI score, mean ± SD	11.2 ± 5.2	11.6 ± 5.5
IGA category, n (%)		
Moderate 3	169 (92.3)	82 (92.1)
Severe 4	14 (7.7)	7 (7.9)
%BSA, mean ± SD	14.7 ± 8.5	14.9 ± 7.7
PP-NRS score, mean ± SD	6.1 ± 2.0	6.1 ± 2.0
PP-NRS <4, n (%)	14 (12.7)	8 (15.1)
PP-NRS ≥4, n (%)	96 (87.3)	45 (84.9)

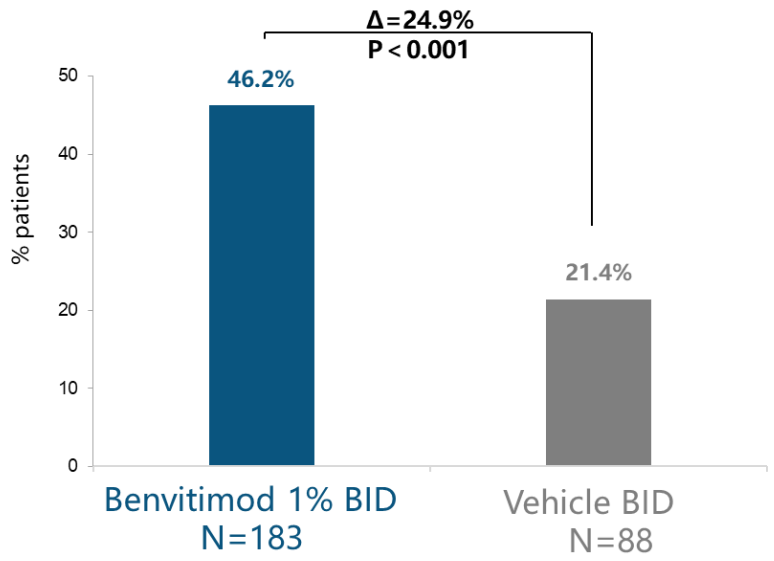
Overall Efficacy: Significant Improvements in Lesions and Itch

Significant EASI-75 Response Rate



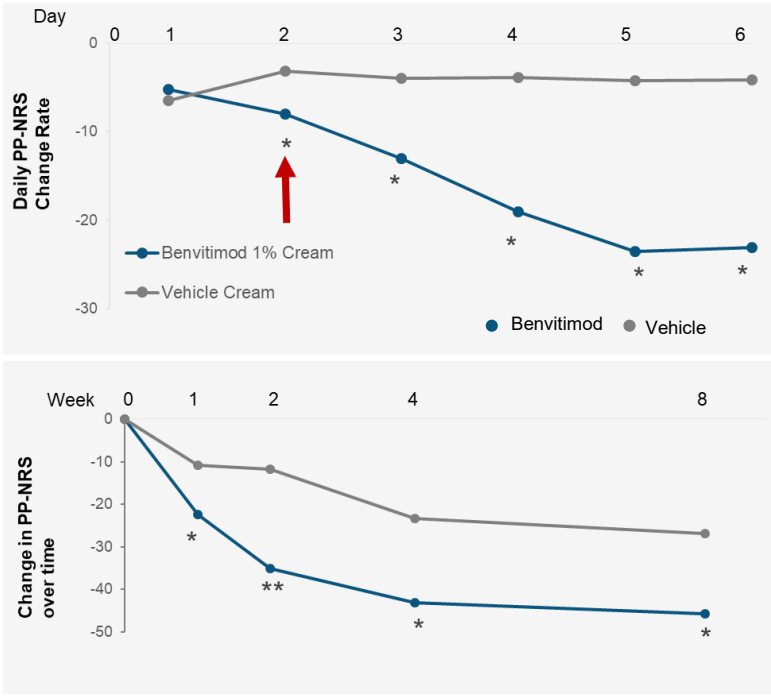
EASI-75 Response Rate at Week 8

High Rate of IGA Response



IGA Response Rate at Week 8

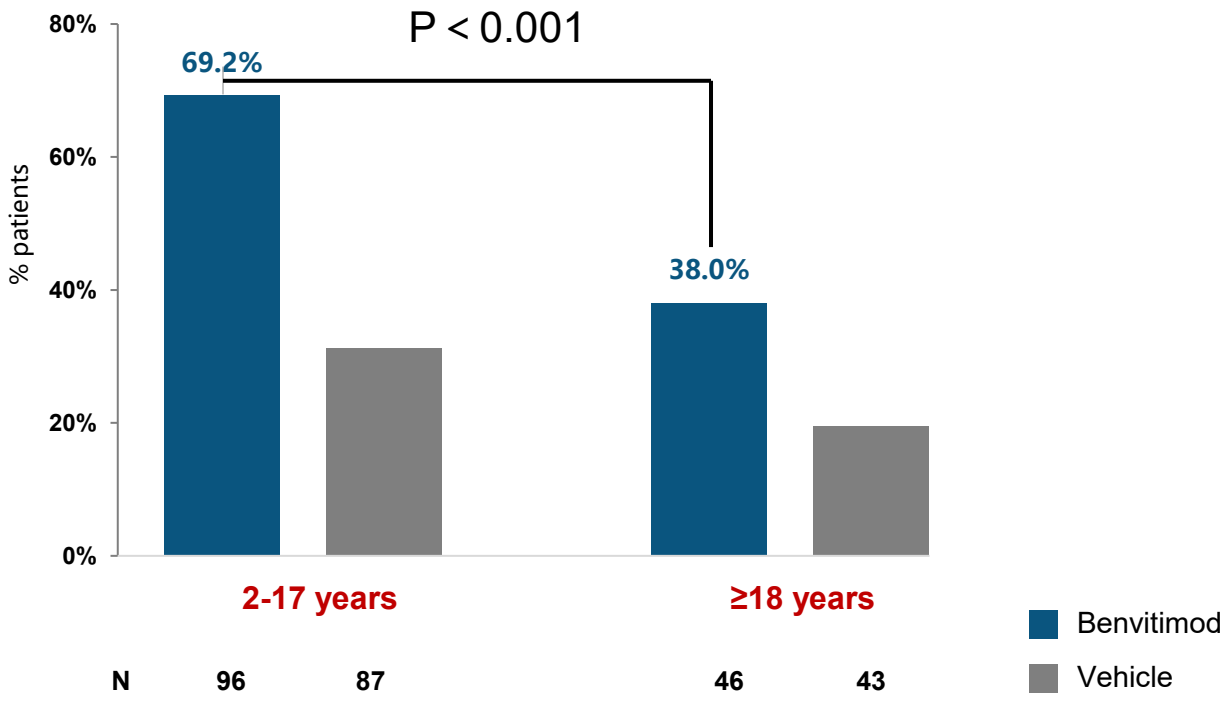
Rapid and Durable Itch Relief



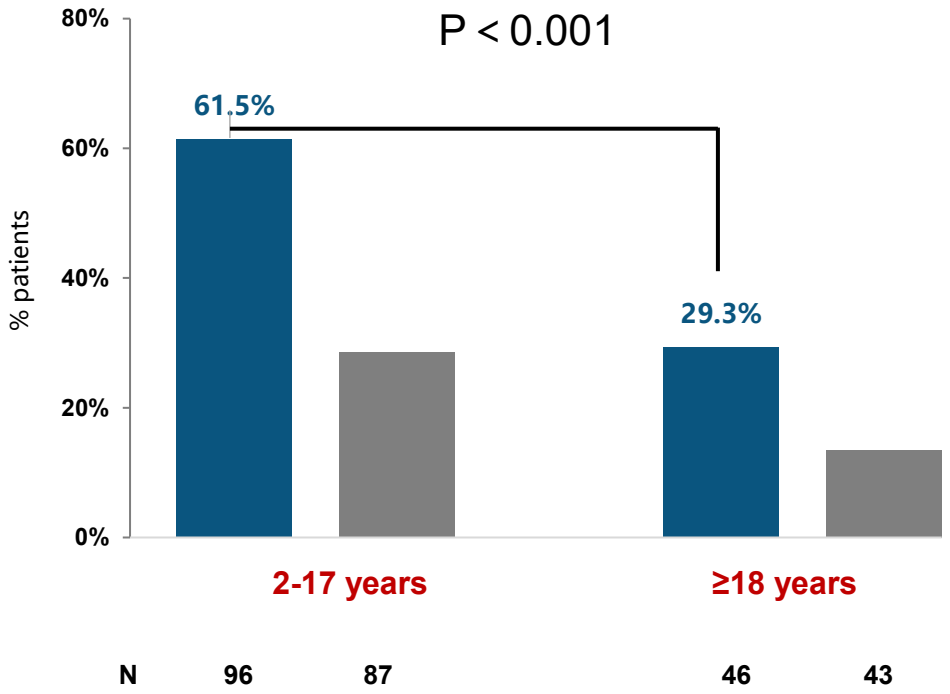
PP-NRS change

Particularly Strong Efficacy Observed in Pediatric Patients

EASI-75 Response Rate at Week 8

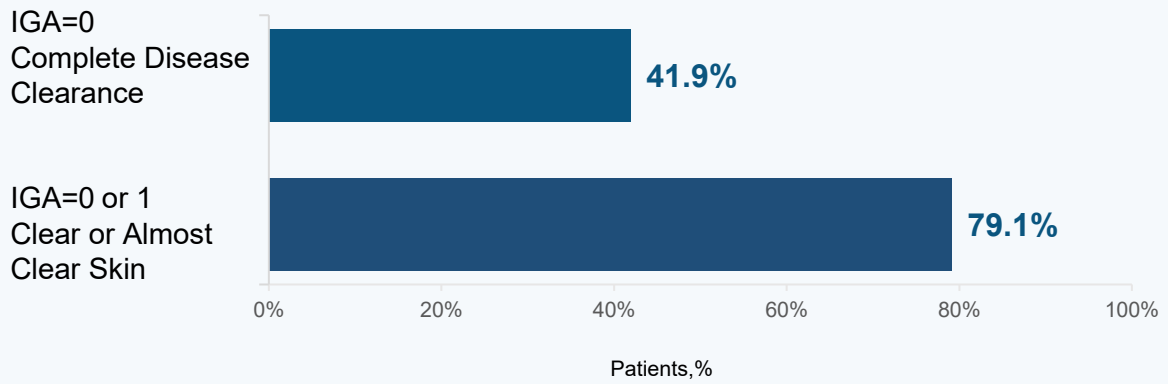


IGA Response Rate at Week 8

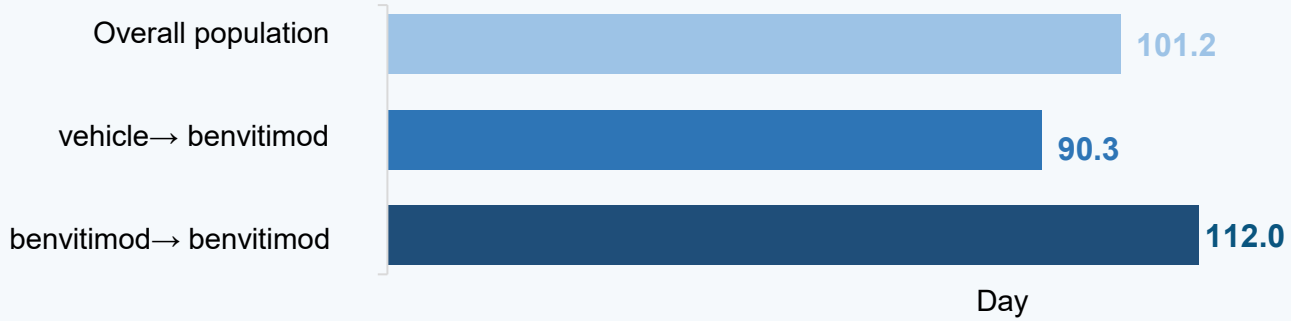


Pediatric patients show a greater improvement than adults，highlighting a **more pronounced therapeutic benefit in the pediatric population**.

Recurrence Control Observed alongside 52-week Follow-ups



Proportion of patients who achieved IGA=0 and IGA=0 or 1



Median duration of the first treatment-free interval

Up to the **52-week** long-term observation period benvitimod delivers **profound and durable disease control** for the majority of patients.

Favorable Safety Profile

- Most adverse events were **mild to moderate** in severity, commonly including folliculitis, contact dermatitis, and application site reactions.
- The long-term safety profile was consistent with previous findings, with **no new safety signals** identified.

	Double-blind Phase (8 weeks)		Extension Phase (44 weeks)
	Benvitimod (n=183)	Vehicle (n=88)	Open Label
Subjects (%)			
ADRs with an incidence of ≥1%			
Folliculitis	7.1	3.4	5.7
Contact dermatitis	3.8	3.4	1.0
Application site pruritus	3.3	1.1	3.1
Application site pain	3.3	0	3.1
Atopic dermatitis	1.1	0	1.0

Summary of Benvitimod in AD Patients

Benvitimod, a novel Acryl Hydrocarbon Receptor Agonist , represents an innovative therapeutic agent for atopic dermatitis

Clinical studies have demonstrated benvitimod's prominent efficacy and favorable safety profile.

The therapeutic effect was particularly pronounced in children, which may be attributed to its synergistic effects on restoring the vulnerable pediatric skin barrier and modulating key inflammatory pathways.

Currently, Benvitimod was approved by NMPA China and FDA, for the treatment of atopic dermatitis in patients aged 2 years and older.