

“WE FELT SO HELPLESS  
WHEN RASHES STARTED  
APPEARING ON HIS  
NECK. TOPICAL RXs  
DIDN'T WORK FOR HIM.”

- Jared's parents

## MEET JARED

Age 3



Not an actual patient.

### OUR STORY

Once we had the diagnosis of moderate-to-severe atopic dermatitis, we tried the topical Rx treatments, but the rashes would return. Then, after several failed treatments, we tried DUPIXENT. What a relief for Jared's skin.

### INDICATION

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

### IMPORTANT SAFETY INFORMATION

**CONTRAINDICATION:** DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

### WARNINGS AND PRECAUTIONS

**Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information.

### HIS SIGNS AND SYMPTOMS

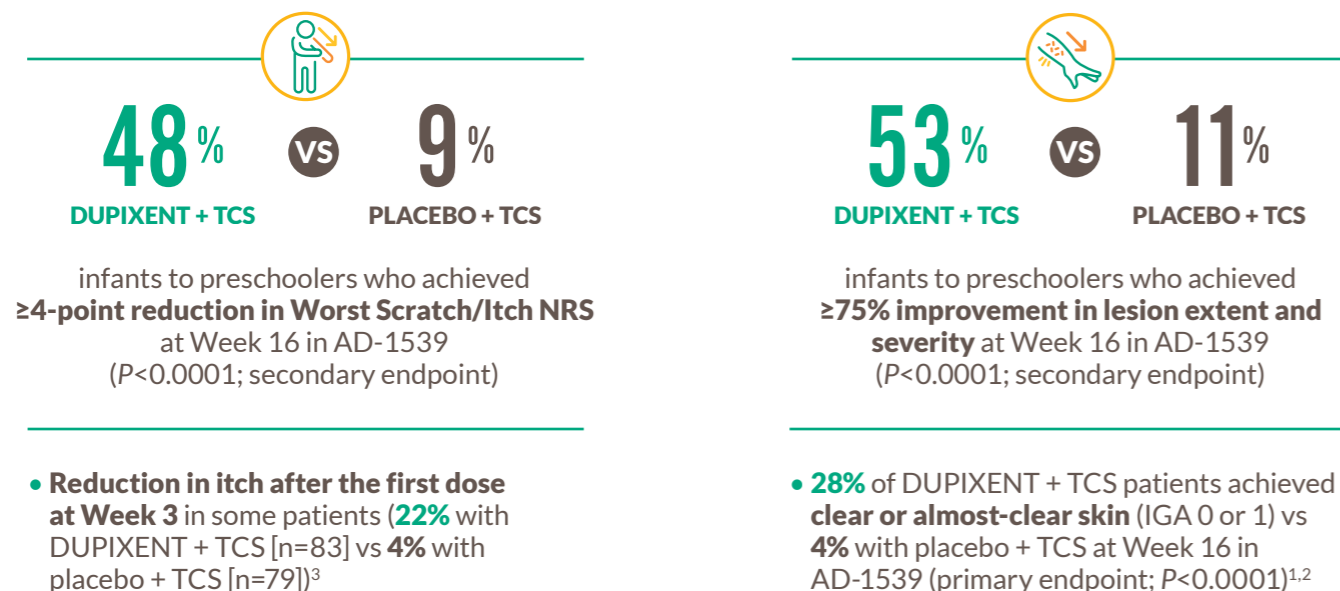
- Rashes with dry, scaly skin
- Relapsing flares
- Persistent itch

### HIS TREATMENT AND GOALS

- Phototherapy, bleach baths, and a special diet—all were ineffective
- Tried topical Rx treatments
- We had to find a way to control the itch and rashes. This was our child; we had to fix it. We needed a treatment for him that would help control his disease

# THE DATA BEHIND THE STORY

## DISEASE CONTROL IN INFANTS TO PRESCHOOLERS (AGED 6 MONTHS TO 5 YEARS) DEMONSTRATED AT WEEK 16 IN 1 CLINICAL TRIAL<sup>1,2</sup>



**Definitive conclusions cannot be made for time points earlier than Week 16 as those data were not multiplicity controlled and P value was nominal.**

**TRIAL DESIGN:** 162 infants to preschoolers (6 months to 5 years) in AD-1539 (16 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT + TCS or placebo + TCS. Patients 15 kg but <30 kg received 300 mg Q4W. Patients 5 kg but <15 kg received 200 mg Q4W. Patients had an IGA score ≥3 on a scale of 0 to 4, an EASI score ≥16 on a scale of 0 to 72, and BSA involvement of ≥10%. At baseline, 23% of infants to preschoolers had an IGA score of 3 (moderate), 77% had an IGA of 4 (severe), mean EASI score was 34.1, and weekly average of daily Worst Scratch/Itch NRS was 7.6 on a scale of 0 to 10.<sup>1,2</sup>

**TRIAL ENDPOINTS:** The primary endpoint was the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) at Week 16. Other endpoints included the proportion of subjects with EASI-75 at Week 16 and ≥4-point improvement in the Worst Scratch/Itch NRS at Week 16.<sup>1,2</sup>

AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; Q4W, once every 4 weeks; TCS, topical corticosteroids.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (cont'd)

**Conjunctivitis and Keratitis:** Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT versus placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in atopic dermatitis patients. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients to report new onset or worsening eye symptoms to their healthcare provider. Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

**Risk Associated with Abrupt Reduction of Corticosteroid Dosage:** Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

# VISIBLE RESULTS

## 4-YEAR-OLD PATIENT—ACHIEVED A 2-POINT IMPROVEMENT IN IGA

Actual patient in a Phase 3 DUPIXENT trial (AD-1539) in infants to preschoolers (aged 6 months to 5 years). Patient was prescribed concomitant low-potency TCS based on the clinical trial program. Patient was considered a clinical responder. Individual results may vary.

### BASELINE: IGA 3 (moderate)



### WEEK 16: IGA 1 (almost clear)



A clinical responder was defined by achieving IGA 0 or 1.<sup>1</sup>



**THE FIRST AND ONLY BIOLOGIC APPROVED TO TREAT UNCONTROLLED MODERATE-TO-SEVERE AD FROM INFANCY TO ADULTHOOD (6+ MONTHS OF AGE)**

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (cont'd)

**Atopic Dermatitis Patients with Co-morbid Asthma:** Advise patients not to adjust or stop their asthma treatments without consultation with their physicians.

**Arthralgia:** Arthralgia has been reported with the use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Advise patients to report new onset or worsening joint symptoms. If symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

**Parasitic (Helminth) Infections:** It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information.

**DUPIXENT**<sup>®</sup>  
(dupilumab) Injection  
200mg · 300mg

# DEMONSTRATED SAFETY PROFILE

The safety profile in infants to preschoolers through Week 16 was similar to that of adults with atopic dermatitis<sup>1</sup>

Adverse reactions occurring in ≥1% of adult patients through Week 16<sup>1</sup>

Adverse reaction	DUPIXENT 300 mg Q2W monotherapy <sup>a</sup>		DUPIXENT 300 mg Q2W + TCS <sup>b</sup>	
	DUPIXENT <sup>c</sup> (n=529) %	Placebo (n=517) %	DUPIXENT + TCS <sup>c</sup> (n=110) %	Placebo + TCS (n=315) %
Injection site reaction	10	5	10	6
Conjunctivitis <sup>d</sup>	10	2	9	5
Blepharitis	<1	<1	5	1
Oral herpes	4	2	3	2
Keratitis <sup>e</sup>	<1	0	4	0
Eye pruritus	1	<1	2	1
Other herpes simplex virus infection <sup>f</sup>	2	1	1	<1
Dry eye	<1	0	2	<1

Treatment-emergent eosinophilia (≥5,000 cells/mcL) was reported in<sup>1</sup>:

- <3% of DUPIXENT-treated subjects and <0.5% of placebo-treated subjects (SOLO 1, SOLO 2, and AD-1021; DRI12544, QUEST, and VOYAGE; SINUS-24 and SINUS-52; PRIME and PRIME2)<sup>g</sup>
- 8% of DUPIXENT-treated subjects and 0% of placebo-treated subjects (AD-1539)

<sup>a</sup> Pooled analysis of SOLO 1, SOLO 2, and AD-1021 (phase 2 dose-ranging study). <sup>b</sup> Analysis of CHRONOS in which subjects were on background TCS therapy. <sup>c</sup> DUPIXENT 600 mg at Week 0, followed by 300 mg every 2 weeks. <sup>d</sup> Conjunctivitis cluster includes conjunctivitis, allergic conjunctivitis, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis, eye irritation, and eye inflammation. <sup>e</sup> Keratitis cluster includes keratitis, ulcerative keratitis, allergic keratitis, atopic keratoconjunctivitis, and ophthalmic herpes simplex. <sup>f</sup> Other herpes simplex virus infection cluster includes herpes simplex, genital herpes, herpes simplex otitis externa, and herpes virus infection, but excludes eczema herpeticum. <sup>g</sup> DRI12544, QUEST, and VOYAGE are part of the asthma clinical trial program; SINUS-24 and SINUS-52 are part of the chronic rhinosinusitis with nasal polyposis clinical trial program; PRIME and PRIME2 are part of the prurigo nodularis clinical trial program.

## DUPIXENT vs placebo: rates of treatment discontinuation and skin infection

Week 16, AD-1539

Comparable rate of <b>discontinuations due to adverse events</b> vs placebo <sup>2</sup>	1% DUPIXENT + TCS	VS	1% Placebo + TCS
Numerically fewer patients developed <b>skin infections</b> vs placebo <sup>2,h</sup>	12% DUPIXENT + TCS	VS	24% Placebo + TCS

- Patients should discontinue DUPIXENT if a clinically significant hypersensitivity reaction occurs or until a parasitic (helminth) infection resolves in a patient who does not respond to anti-helminth treatment<sup>1</sup>

<sup>h</sup> Data reflect adjudicated nonherpetic skin infections through Week 16.

 THE FIRST AND ONLY BIOLOGIC WITH A DEMONSTRATED SAFETY PROFILE FOR INFANTS TO PRESCHOOLERS (6 MONTHS TO 5 YEARS OF AGE) IN ATOPIC DERMATITIS

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (cont'd)

**Vaccinations:** Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating DUPIXENT. Avoid use of live vaccines in patients treated with DUPIXENT.

# ATTRIBUTES AND CONSIDERATIONS



**NOT AN IMMUNOSUPPRESSANT<sup>1</sup>**



**NO INITIAL LAB TESTING OR ONGOING LAB MONITORING**  
according to the Prescribing Information<sup>1</sup>



**NO KNOWN DRUG-TO-DRUG INTERACTIONS<sup>1</sup>**

- Not metabolized through the liver or excreted through the kidneys



**NO BOXED WARNING<sup>1</sup>**

Please see additional Warnings and Precautions in the Prescribing Information and Important Safety Information throughout.

## SELECT IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

## IMPORTANT SAFETY INFORMATION

**ADVERSE REACTIONS:** The most common adverse reactions (incidence ≥1%) in patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia. The safety profile in pediatric patients through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile of DUPIXENT ± TCS in pediatric patients observed through Week 52 was consistent with that seen in adults with atopic dermatitis, with hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation.

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. To enroll or obtain information call 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/dupixent/>. Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information.

**References:** 1. DUPIXENT Prescribing Information. 2. Paller AS, Simpson EL, Siegfried EC, et al. Dupilumab in children aged 6 months to younger than 6 years with uncontrolled atopic dermatitis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2022;400(10356):908-919. 3. Data on file, Regeneron Pharmaceuticals, Inc.

**DUPIXENT<sup>®</sup>**  
(dupilumab) Injection  
200mg · 300mg



WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH, DUPIXENT:  
**YOUR FIRST CHOICE**  
TO ADEQUATELY CONTROL THIS CHRONIC, SYSTEMIC DISEASE



**Significant itch reduction and skin clearance<sup>1,2</sup>**

- **48%** of infants to preschoolers treated with DUPIXENT + TCS (n=83) **achieved ≥4-point reduction in Worst Scratch/Itch NRS** vs **9%** with placebo + TCS (n=79) at Week 16 in AD-1539 (P<0.0001; secondary endpoint)
- **28%** of infants to preschoolers treated with DUPIXENT + TCS (n=83) **achieved clear or almost-clear skin (IGA 0 or 1)** vs **4%** with placebo + TCS (n=79) at Week 16 in AD-1539 (P<0.0001; primary endpoint)

**52**  
WEEKS

**A demonstrated safety profile<sup>1</sup>**

- **Most common adverse reactions (incidence ≥1%)** are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia
- The 52-week safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile
- The safety profile in infants to preschoolers through Week 16 (in a pivotal trial) and Week 52 (in an open-label extension trial, AD-1434) was similar to that of adults with atopic dermatitis
  - In AD-1434, hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) was reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation

**#1** prescribed biologic  
by dermatologists<sup>3,a</sup>

**6 YEARS**  
since initial FDA approval in AD<sup>1,b</sup>



**NOT AN  
IMMUNOSUPPRESSANT<sup>1</sup>**



**NO REQUIREMENT FOR  
INITIAL LAB TESTING  
OR ONGOING LAB  
MONITORING**, according to  
the Prescribing Information<sup>1</sup>



**NO BOXED WARNING<sup>1</sup>**  
Please see additional Warnings  
and Precautions in the Prescribing  
Information and Important Safety  
Information throughout.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

**Please see additional Important Safety Information throughout and click [here](#) for full Prescribing Information.**

<sup>a</sup> IQVIA NBRx data as of [December 2022].

<sup>b</sup> FDA approved since 2017 for adults, 2019 for adolescents (aged 12-17 years), 2020 for children (aged 6-11 years), and 2022 for infants to preschoolers (aged 6 months to 5 years) with uncontrolled moderate-to-severe atopic dermatitis.



**SEE HOW OTHER PATIENTS LIKE  
JARED ACHIEVE CHANGE IN ITCH  
AND SKIN LESIONS WITH DUPIXENT**

**sanofi**

**REGENERON**<sup>®</sup>