UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 4, 2014 (March 4, 2014)

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York		
(State or other jurisdiction of incorporation)		
000-19034		**13-3444607**
(Commission File Number)		**(I.R.S. Employer Identification No.)**
777 Old Saw Mill River Road, Tarrytown, New York		**10591-6707**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (914) 847-7000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On March 4, 2014, at the annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) held in San Diego, California, data from a Phase 2a trial evaluating dupilumab, a human monoclonal antibody, in patients with atopic dermatitis were presented at an oral session by Prof. Diamant Thaçi, University of Lübeck, Germany. A copy of the slides is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Presentation entitled “Dupilumab Monotherapy in Adults with Moderate-to-Severe Atopic Dermatitis: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study.”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa
Joseph J. LaRosa
Senior Vice President, General Counsel and Secretary

Date: March 4, 2014

EXHIBIT INDEX

Number	Description
99.1	Presentation entitled “Dupilumab Monotherapy in Adults with Moderate-to-Severe Atopic Dermatitis: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study.”

Exhibit 99.1

Dupilumab Monotherapy in Adults with Moderate-to-Severe Atopic Dermatitis: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study

Thomas Bieber,[1] Diamant Thaçi,[2] Neil Graham,[3] Gianluca Pirozzi,[4] Ariel Teper,[4] Haobo Ren,[3] Neil Stahl,[3] George Yancopoulos,[3] Allen Radin[3]

[1]Department of Dermatology and Allergy, Friedrich-Wilhelms University of Bonn, Bonn, Germany; [2]Comprehensive Center Inflammation Medicine, University of Lübeck, Lübeck, Germany; [3]Regeneron Pharmaceuticals, Inc., Tarrytown, United States; [4]Sanofi, Bridgewater, United States

Disclosures

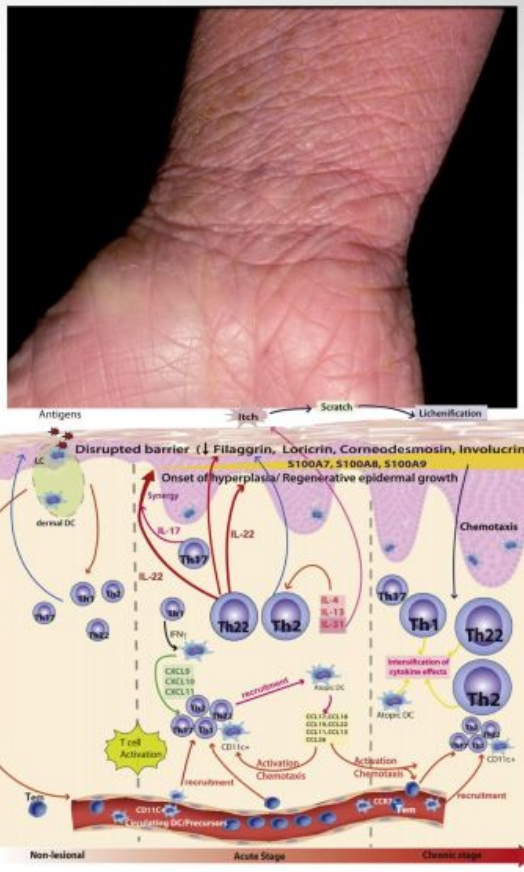
- D Thaçi is a consultant for Astellas, Novartis, Regeneron, Celgene, Abbott, Pfizer, Janssen-Cilag, MSD, Leo-Pharma
- T Bieber is a consultant for Regeneron, Basilea, L'Oréal, Oxagen, Bioalliance, Stern Biologics and a speaker for Astellas
- N Graham, H Ren, N Stahl, G Yancopoulos, and A Radin are employees and shareholders of Regeneron
- G Pirozzi and A Teper are employees and shareholders of Sanofi
- Study (NCT01548404) funded by Regeneron Pharmaceuticals, Inc. and Sanofi

Introduction

- Moderate-to-severe atopic dermatitis (AD) is characterized by eczematous dermatitis with intractable pruritus associated with sleep disturbance and lower quality-of-life

- For many patients, current therapies are inadequate and can be associated with unwanted side effects

- IL-4 and IL-13 are thought to be central to T-helper 2 (Th2) inflammation, which mediates many features of AD

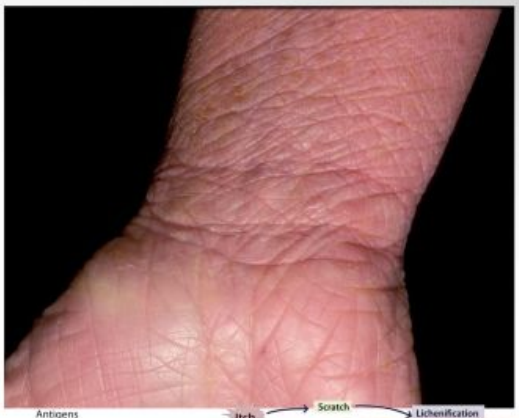


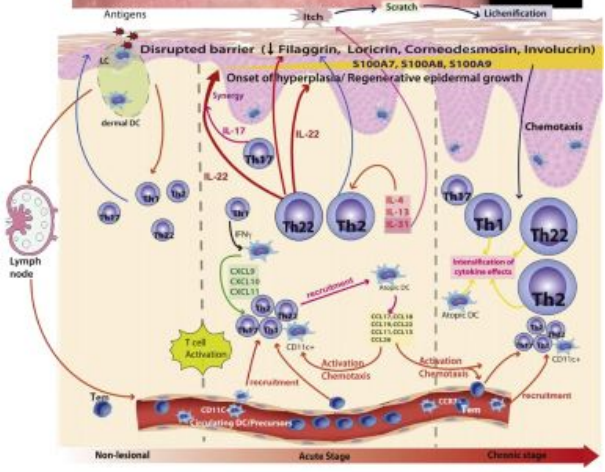
Introduction

- Dupilumab is a fully human monoclonal antibody targeting the IL-4 receptor alpha subunit (IL-4Rα), thus blocking the intracellular signaling of both IL-4 and IL-13

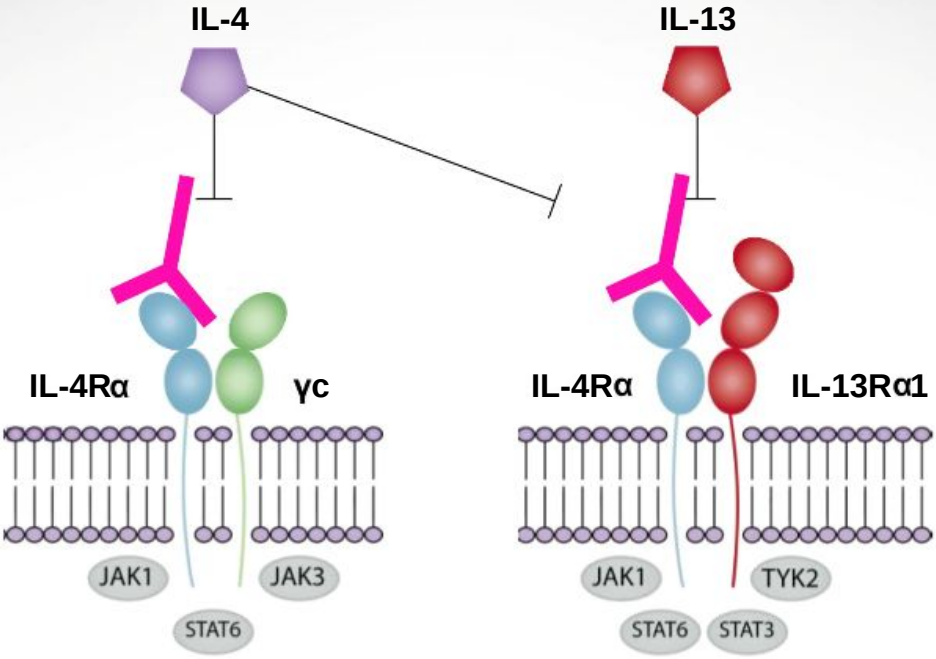
- Earlier clinical trials indicated that dupilumab monotherapy had an acceptable safety profile and was efficacious in patients with moderate-to-severe AD who cannot be adequately controlled with topical medications

- We assessed the clinical efficacy of repeated subcutaneous doses of dupilumab monotherapy for 12 weeks in adult patients with moderate-to-severe AD poorly controlled by topical agents





Dupilumab (anti-IL-4Rα) blocks the IL-4/IL-13 receptor/ligand system



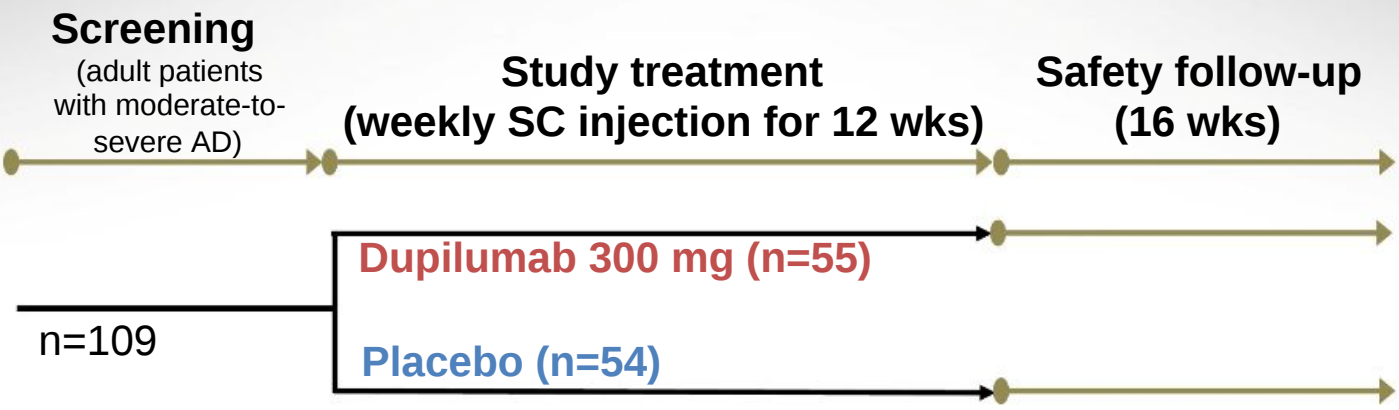
Type I Receptor

B cells, T cells, Monocytes, Eosinophils, Fibroblasts

Type II Receptor

Epithelial cells, Smooth muscle cells, Fibroblasts, Monocytes, Activated B cells

Dupilumab Monotherapy in Adults with Moderate-to-Severe Atopic Dermatitis: A European 12-Week, Randomized, Double-Blind, Placebo-Controlled Phase 2a Study (NCT01548404)



Primary endpoint: Percent change in EASI from baseline to week 12

Secondary endpoints: Changes from baseline to week 12 in EASI, SCORAD, %BSA, pruritus NRS, 5-D pruritus scale, proportion of patients achieving EASI-50/75, IGA 0-1; and safety

EASI=Eczema Area Severity Index; SCORAD=scoring of atopic dermatitis; BSA = baseline body surface area; NRS=numeric rating scale; EASI-50 ≥ 50% reduction in EASI score; EASI-75 ≥ 75% reduction in EASI score
IGA 0-1=Investigator's Global Assessment score of 0 ("clear") or 1 ("almost clear")

Key inclusion/exclusion criteria

Inclusion

- Male or female ≥18 yrs
- Chronic AD ≥ 3 yrs
- EASI ≥ 16
- IGA ≥ 3
- ≥ 10% BSA of AD involvement
- History of inadequate response to a stable (≥1 month) regimen of topical corticosteroids or calcineurin inhibitors within 3 months prior to screening visit

Exclusion

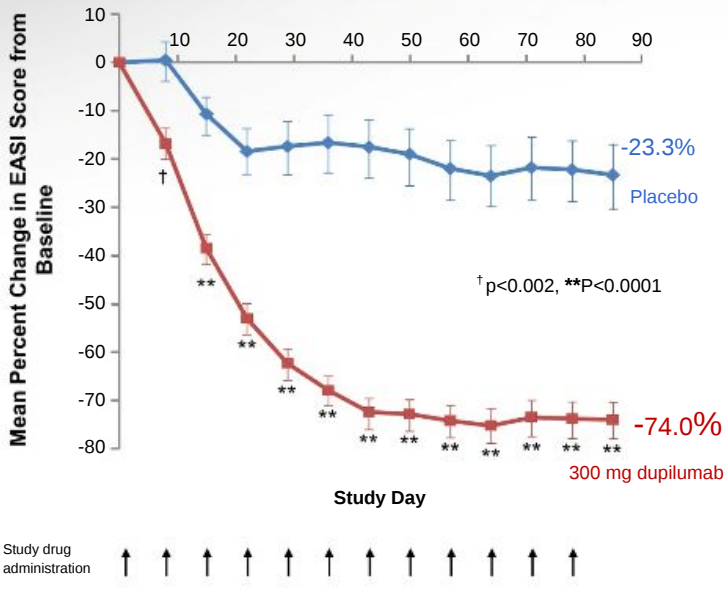
- Prior treatment with dupilumab
- Acute or chronic infections
- Recent treatment with topical corticosteroids, calcineurin inhibitors, immunosuppressive/ immunomodulating drugs
- Significant co-morbidities or lab abnormalities

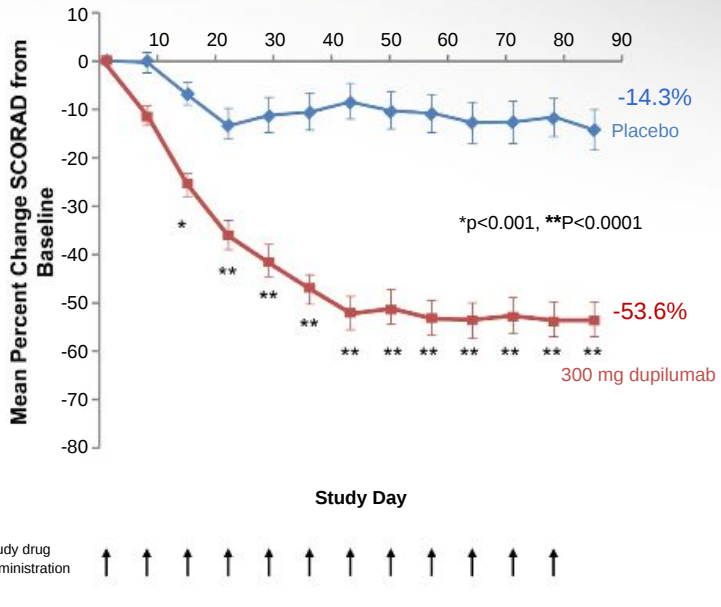
Baseline demographics and disease characteristics*

	Placebo (n=54)	Dupilumab 300 mg (n=55)
Age, yrs	39.4 (12.3)	33.7 (10.4)
Caucasian, n (%)	54 (100)	55 (100)
Men, n (%)	27 (50.0)	31 (56.4)
BMI, kg/m^2	24.51 (4.64)	25.89 (4.84)
AD diagnosis age, yrs	14.4 (18.35)	6.6 (10.52)
EASI score (0-72)	30.8 (13.63)	28.4 (13.57)
IGA score (0-5)	4.0 (0.69)	3.9 (0.67)
SCORAD score (0-103)	69.1 (13.38)	66.7 (13.82)
%BSA of AD	50.8 (24.14)	46.8 (24.55)
Pruritus (NRS) score (0-10)	5.00 (1.40)	6.43 (2.00)
5-D Pruritus Scale (5-25)	18.7 (3.50)	18.4 (3.04)

***Values shown are mean (SD) or n (%).** EASI=Eczema Area Severity Index (range 0-72); IGA=Investigator's Global Assessment (range 0-5); SCORAD=scoring of atopic dermatitis (range 0-103); BSA = baseline body surface area; NRS=numeric rating scale (range 0-10); 5-D Pruritus Scale (range 5-25)

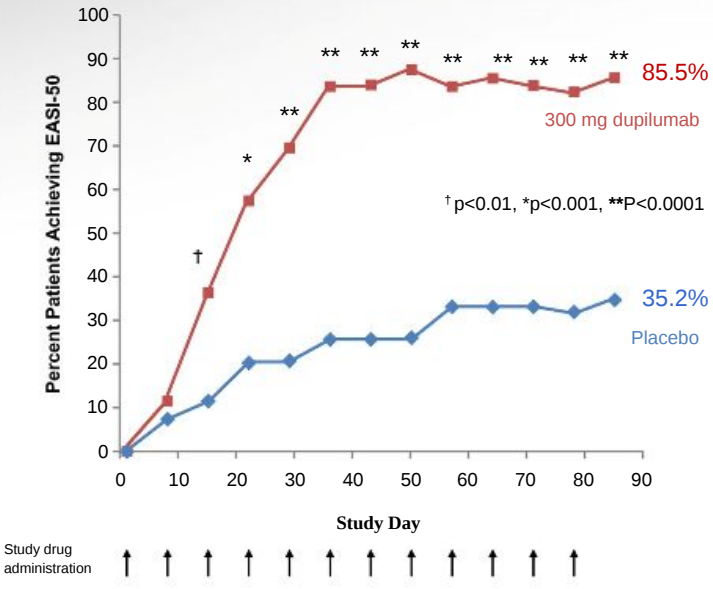
Percent change in EASI and SCORAD scores over 12 weeks

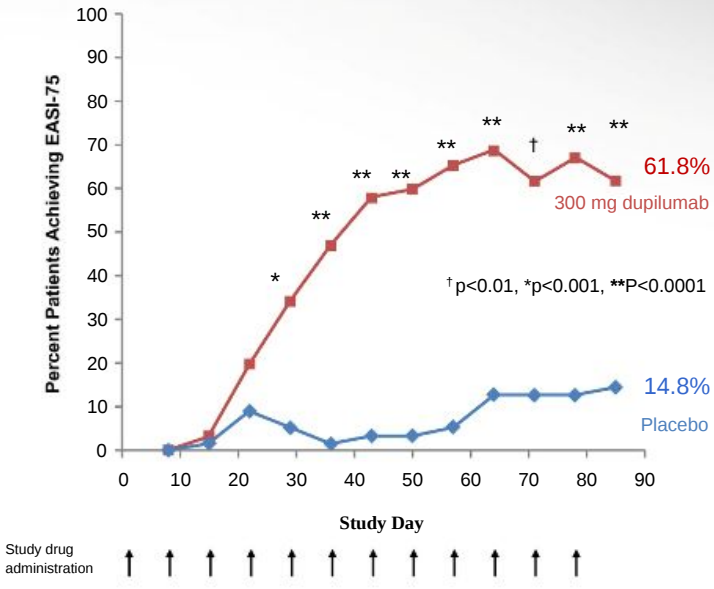




*, †**(LOCF)

Proportion of patients who achieve EASI-50 and EASI-75 over 12 weeks

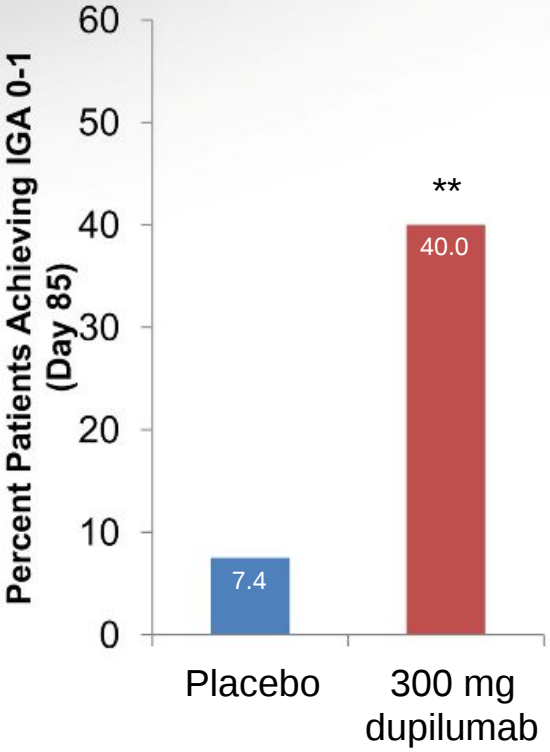


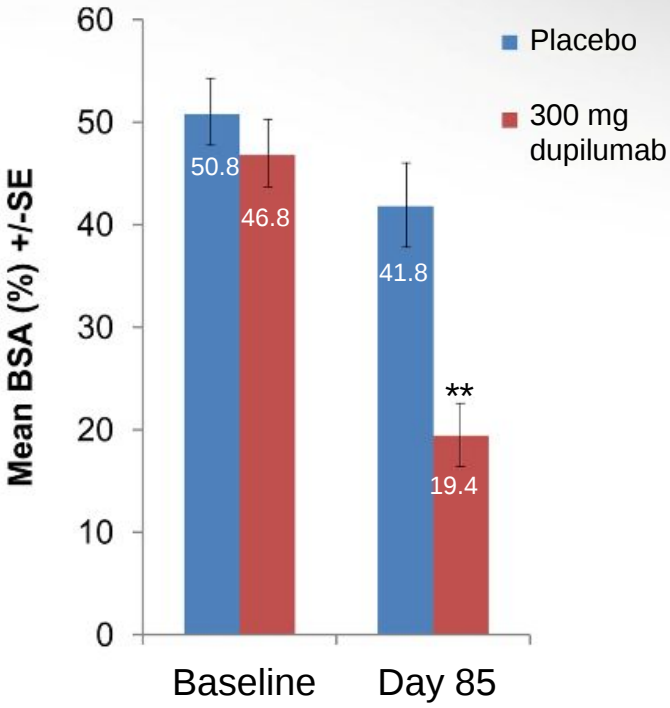


*, †**(LOCF)

EASI-50 ≥ 50% reduction in EASI score; EASI-75 ≥ 75% reduction in EASI score

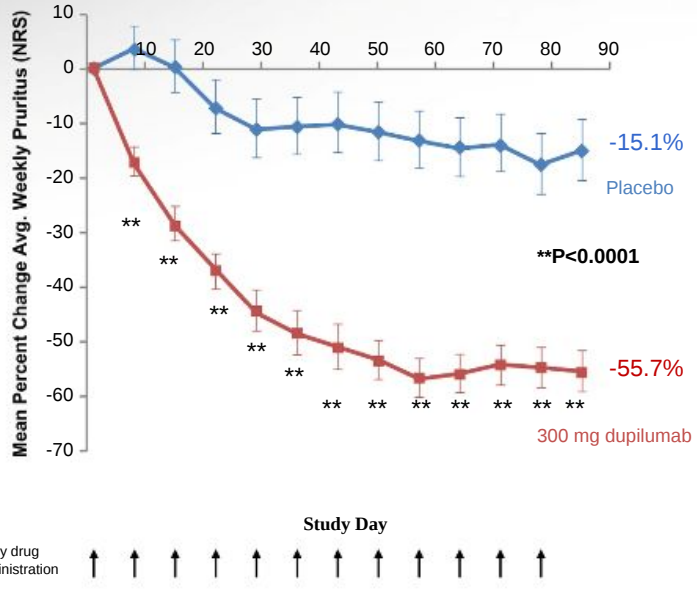
Percent patients achieving IGA 0-1 and mean BSA(%) at day 85

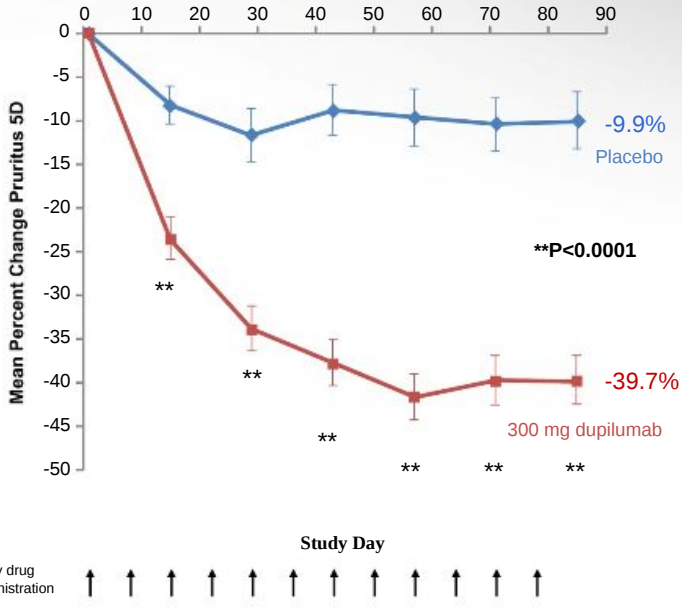




** p<0.0001; LOCF

Percent change in NRS and 5-D pruritus scores over 12 weeks





NRS=numeric rating scale

**(LOCF)

Treatment emergent adverse events over 28 weeks

	Placebo (n = 54)	Dupilumab 300 mg (n = 55)
Total number of AEs	159	163
Total number of AEs related to study drug	45	49
Total number of serious AEs	11	1
Deaths	0	0
Number (%) of patients discontinued from study		
Due to AE	3 (5.6)	1 (1.8)
Due to Lack of Efficacy	23 (42.6)	7 (12.7)
Infections and infestations*	31 (57.4)	31 (56.4)
Most common AEs (≥10%)		
Nasopharyngitis	10 (18.5)	22 (40.0)
Headache	7 (13.0)	9 (16.4)
Conjunctivitis	2 (3.7)	7 (12.7)

* System Organ Class

Skin infections were less frequent with dupilumab treatment compared to placebo

	Placebo (n = 54)	Dupilumab 300 mg (n = 55)
Total number of patients (%) with skin infections	13 (24.1%)	3 (5.5%)
Total number of skin infections*	14	3
Impetigo	3	1
Skin bacterial infection	3**	0
Eczema herpeticum	2**	0
Skin infection	2	0
Anorectal cellulitis	1	0
Cellulitis	1**	0
Infected dermatitis	1	0
Folliculitis	1	0
Infected blister	0	1
Pustular rash	0	1

*based on Standardized MedDRA Query; **one occurrence considered both severe and serious

Serious Adverse Events

	Placebo (n = 54)	Dupilumab 300 mg (n = 55)
Number of SAEs	**11**	**1**
Patients with SAE*, n (%)	**7 (13.0%)**	**1 (1.8%)**
Facial bones fracture [traumatic]	**0**	**1 (1.8%)**
Angina pectoris	**1 (1.9%)**	**0**
Cellulitis	**1 (1.9%)**	**0**
Eczema herpeticum	**1 (1.9%)**	**0**
Skin bacterial infection	**1 (1.9%)**	**0**
Renal failure	**1 (1.9%)**	**0**
Asthmatic crisis	**1 (1.9%)**	**0**
Lung disorder [pneumopathy]	**1 (1.9%)**	**0**
Dermatitis Atopic	**4 (7.4%)**	**0**

* MedDRA Preferred Term; all SAEs were classified as such due to hospitalization

Summary

- In this Phase 2a study of 109 European adults with moderate-to-severe AD, dupilumab (anti-IL-4Rα) 300 mg SC weekly was associated with rapid and marked sustained improvement in EASI, SCORAD, IGA, and BSA%, and pruritus
- At 12 weeks, the dupilumab group achieved statistically superior clinical outcomes compared to the placebo group in all measures of disease activity and pruritus
- There were notably fewer patients with skin infections associated with dupilumab (5.5%) treatment compared with placebo (24.1%)
- There were no infection related SAEs or eczema herpeticum in the dupilumab group
- In the placebo group, 3 patients with skin infections and 4 patients with AD exacerbations required hospitalization
- The most common TEAEs were nasopharyngitis, headache, and conjunctivitis

Acknowledgements

All participating patients

Investigators

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Melissa Hager
Jennifer Hamilton
Richard Kao
Jacquie Kuritzky
Linda Williams

BACK-UP

The 5-D itch scale: a new measure of pruritus

- 5-D Pruritus Scale: Duration, Degree, Direction, Disability, Distribution
  - Single-item domain scores (duration, degree and direction) are equal to the value of the response choice
  - The disability domain includes four items that assess the impact of itching on daily activities: sleep, leisure/social activities, housework/errands and work/school
  - For the distribution domain, the number of affected body parts is tallied
- 5-D scores can potentially range between 5 (no pruritus) and 25 (most severe pruritus)

Elman S et al. *Brit J Dermat* 2010;162:587-93.