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): October 3, 2013 (October 3, 2013)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road,
Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

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:

☐ 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 October 3, 2013, at the 22nd Congress of the European Academy of Dermatology and Venereology held in Istanbul, Turkey, data from a Phase 2 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 that were presented is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Presentation entitled “Safety and efficacy of dupilumab for moderate-to-severe atopic dermatitis in patients using topical corticosteroids (TCS): Greater efficacy observed with combination therapy compared to TCS alone.”

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 hereunto duly authorized.

Date: October 3, 2013

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Senior Vice President, General Counsel and Secretary

Exhibit Index

Number	Description
99.1	Presentation entitled “Safety and efficacy of dupilumab for moderate-to-severe atopic dermatitis in patients using topical corticosteroids (TCS): Greater efficacy observed with combination therapy compared to TCS alone.”

Safety and efficacy of dupilumab for moderate-to-severe atopic dermatitis in patients using topical corticosteroids (TCS): Greater efficacy observed with combination therapy compared to TCS alone

Diamant Thaçi,[1] Margitta Worm,[2] Haobo Ren,[3] Steven Weinstein,[3] Neil Graham,[3] Gianluca Pirozzi,[4] Franck Skobieranda,[4] Marius Ardeleanu[3]

[1]Universität zu Lübeck, Lübeck, Germany; [2]Charite-Universitätsmedzin Berlin, Berlin, Germany; [3]Regeneron Pharmaceuticals, Inc., Tarrytown, USA; [4]Sanofi, Bridgewater, USA

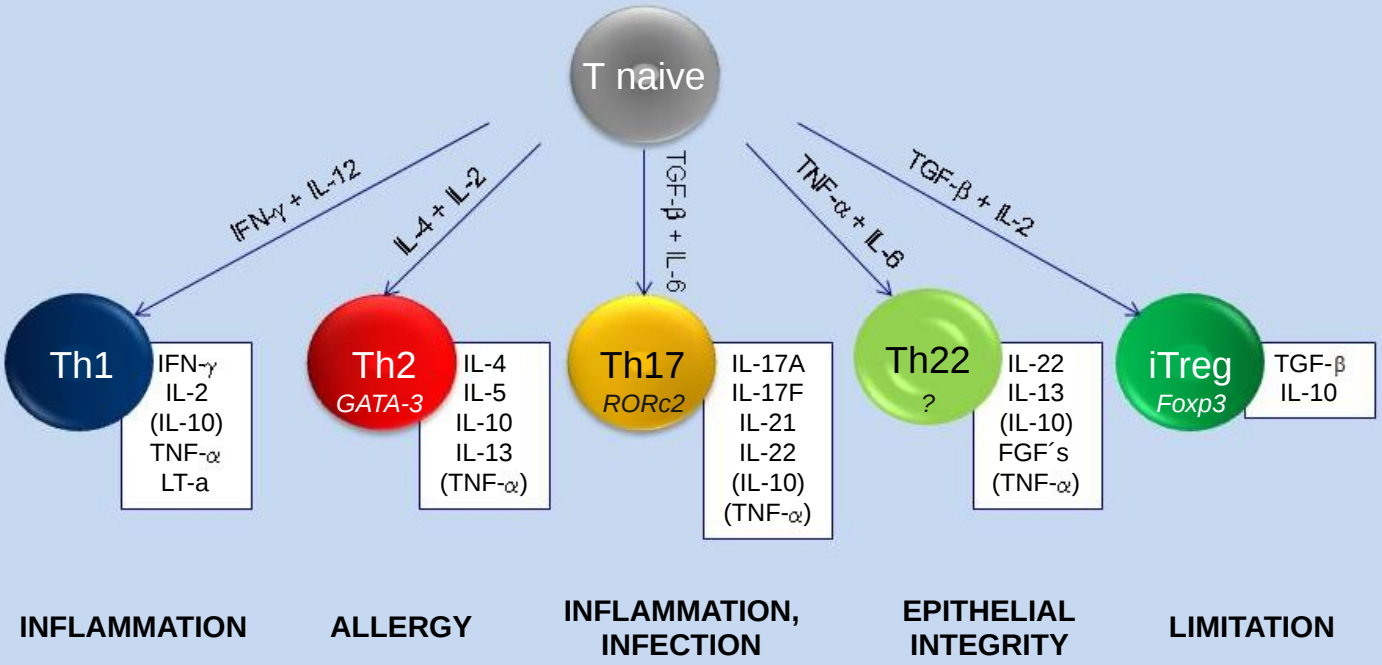
Disclosures

- D Thaçi is a consultant for Astellas, Novartis, Regeneron, Celgene, Abbott, Pfizer, Janssen-Cilag, MSD, Leo-Pharma
- M Worm has nothing to disclose
- H Ren, S Weinstein, N Graham, and M Ardeleanu are employees and shareholders of Regeneron
- G Pirozzi is an employee and shareholder of Sanofi
- F Skobieranda was an employee of Sanofi when the study was conducted
- Study (NCT01639040) funded by Regeneron Pharmaceuticals, Inc. and Sanofi

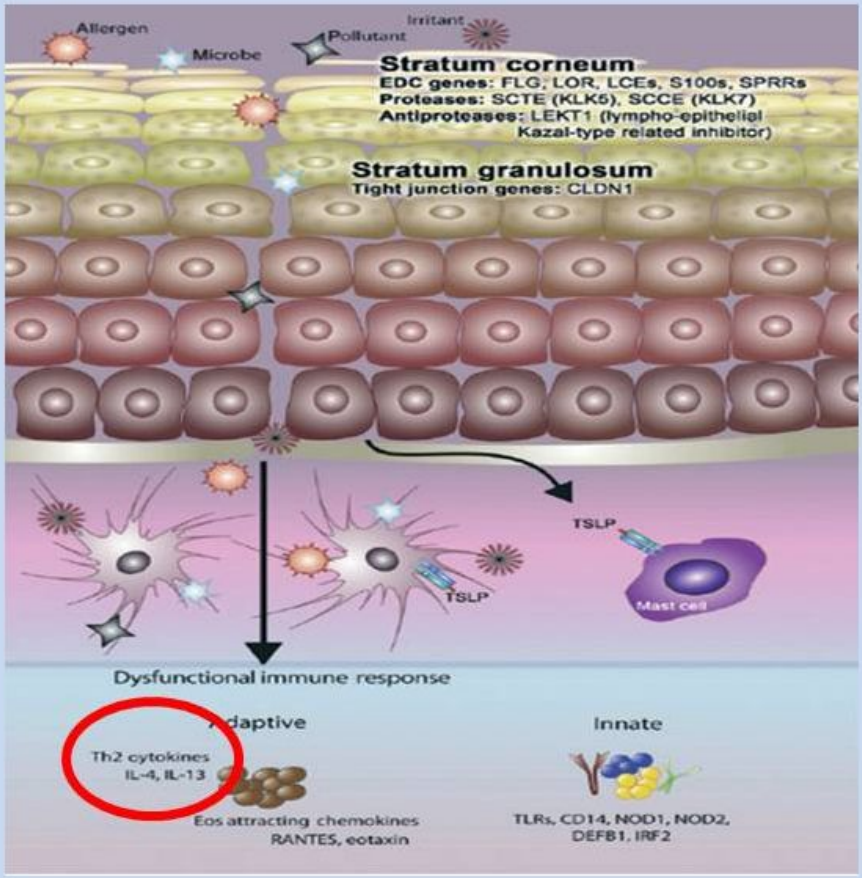
Introduction

- 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
- 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
- Since topical corticosteroids (TCS) are commonly used in AD, we assessed the safety and efficacy of dupilumab co-administered with TCS

T cells in immune mediated diseases

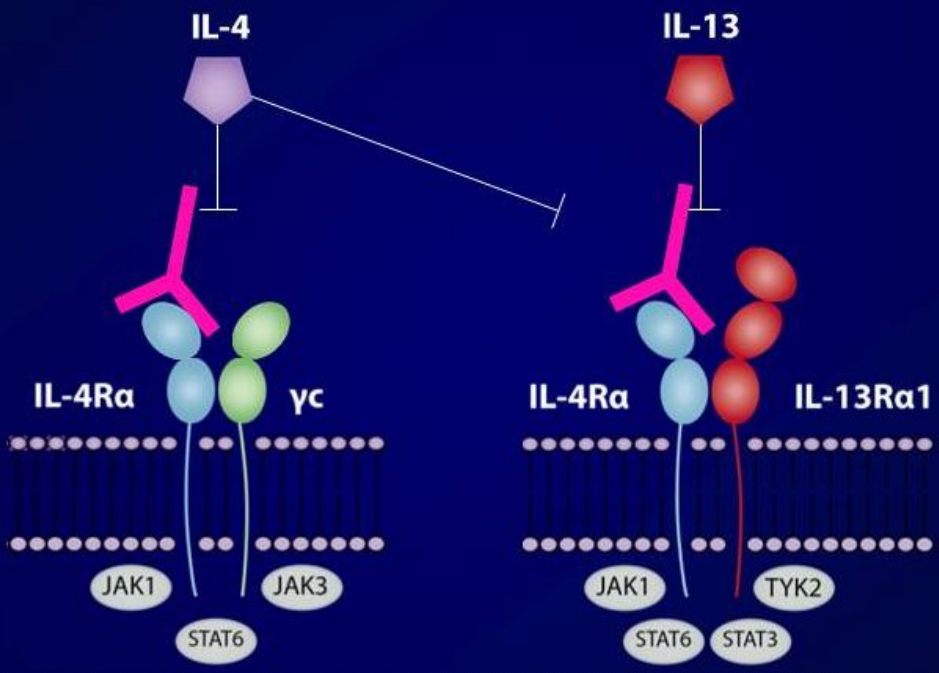


Atopic dermatitis: a disease of altered skin barrier and immune dysregulation



Boguniewicz M, Leung DM. Immunol Rev. 2011 Jul;242(1):233-46.

Dupilumab blocks the IL-4/IL-13 receptor/ligand system



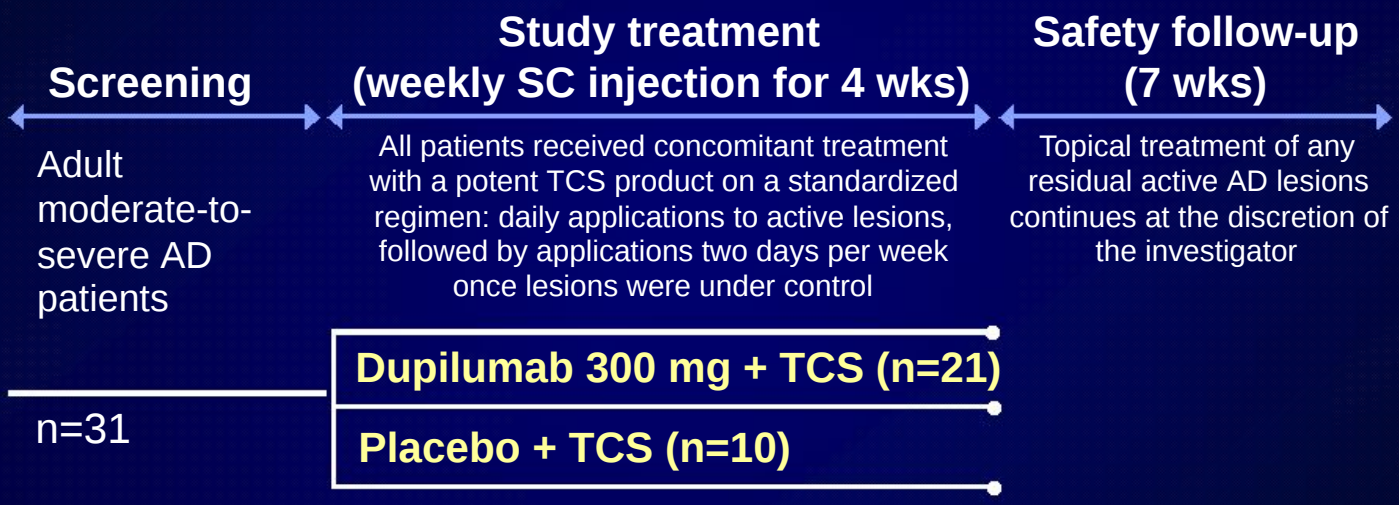
Type I Receptor

B cells, T cells, Monocytes, Eosinophils, Fibroblasts

Type II Receptor

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

Randomized, double-blind, parallel-group, placebo-controlled study (NCT01639040) conducted in EU



Study endpoints:

- Primary endpoint was incidence and severity of adverse events (AEs)
- Exploratory efficacy endpoints included EASI-50, IGA ≤1, SCORAD score

Key inclusion/exclusion criteria

Inclusion

- Male or female ≥ 18 yrs
- Chronic AD > 2 yrs
- IGA ≥ 3
- SCORAD > 20
- ≥ 10% BSA of AD involvement
- Active AD lesion(s) for which treatment with potent TCS is indicated

Exclusion

- Hypersensitivity to TCS
- ≥ 50% of the cumulative lesional surface located on face, flexural, or genital areas (generally unsuitable for treatment with potent TCS)
- Acute or chronic infections
- Recent treatment with immuno-suppressive/immunomodulating drugs
- Significant co-morbidities or lab abnormalities

Baseline demographics

	Placebo + TCS (n=10)	Dupilumab SC 300 mg +TCS (n=21)
Mean age, yrs (SD)	37.8 (16.7)	36.0 (11.3)
Race, n (%)		
Caucasian	10 (100%)	20 (95.2%)
Non-Caucasian	0	1 (4.8%)
Gender, n (%)		
Male	5 (50.0%)	8 (38.1%)
Female	5 (50.0%)	13 (61.9%)
Mean BMI, kg/m^2 (SD)	23.92 (3.47)	25.26 (3.26)

Baseline disease characteristics

[mean (SD)]

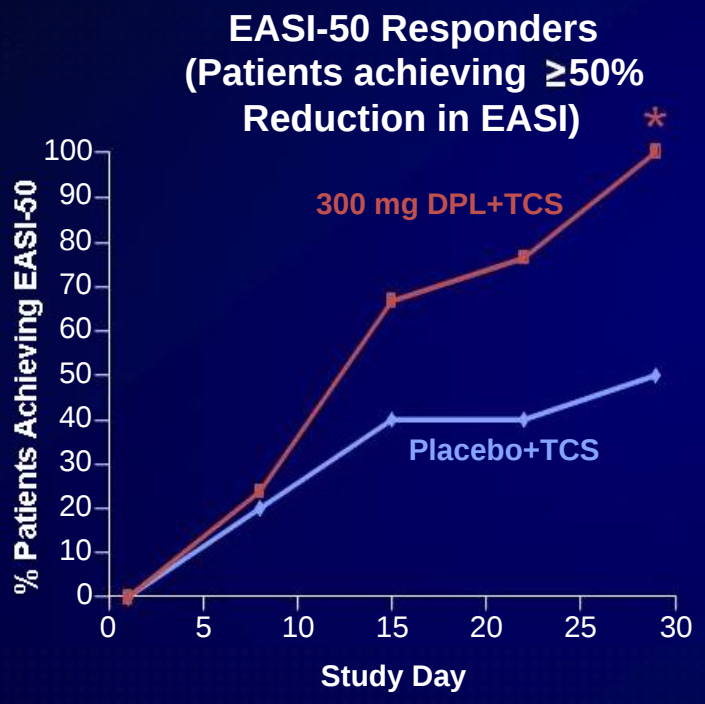
	Placebo + TCS (n=10)	Dupilumab SC 300 mg +TCS (n=21)
AD duration, yrs	32.4 (16.8)	30.9 (13.0)
EASI score (0-72)	24.10 (12.70)	23.12 (12.35)
IGA score (0-5)	3.35 (0.47)	3.43 (0.60)
SCORAD score (0-103)	58.20 (13.83)	66.31 (13.01)
% BSA of AD	38.85 (24.05)	40.43 (20.91)
Pruritus Numeric Rating Scale (NRS) score (0-10)	5.00 (1.40)	6.43 (2.00)

EASI=Eczema Area Severity Index; IGA=Investigator's Global Assessment; SCORAD=scoring of atopic dermatitis; BSA = baseline body surface area; NRS=numeric rating scale

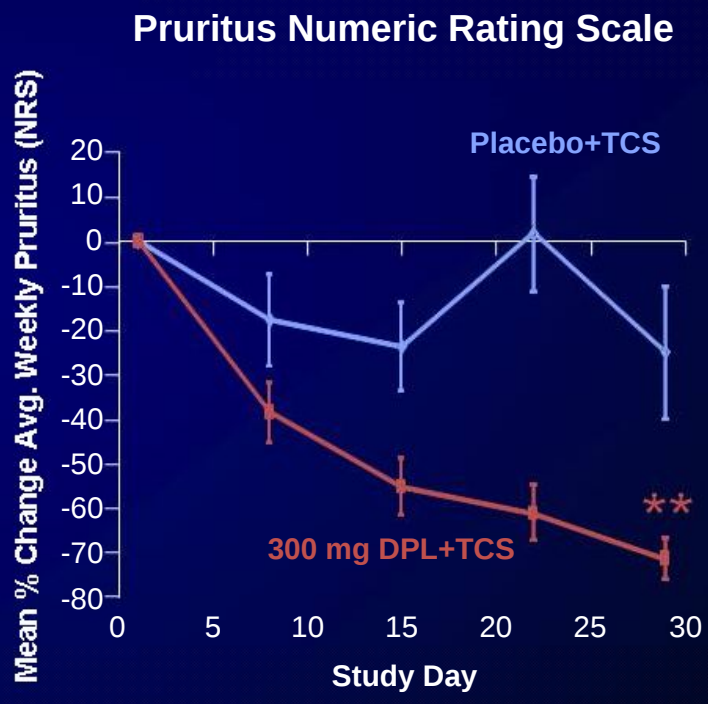
Treatment emergent adverse events

	Placebo + TCS (n = 10)	Dupilumab + TCS (n = 21)
Total number of AEs	14	41
Total number of serious AEs	1	0
Deaths	0	0
Number (%) of patients discontinued from study due to AE	1 (10.0%)	0
Number (%) of patients with:		
▪ **Any AE**	7 (70.0)	12 (57.1)
▪ **Any serious AE**	1 (10.0)	0
▪ **Most common AEs (≥ 5% in dupilumab groups)**		
• Nasopharyngitis	2 (20.0)	5 (23.8)
• Headache	1 (10.0)	3 (14.3)
• Oropharyngeal pain	1 (10.0)	3 (14.3)
• Rhinitis	0	2 (9.5)
• Cough	0	2 (9.5)
• Influenza	0	2 (9.5)
• Somnolence	0	2 (9.5)

Dupilumab+TCS significantly improved measures of efficacy vs TCS alone



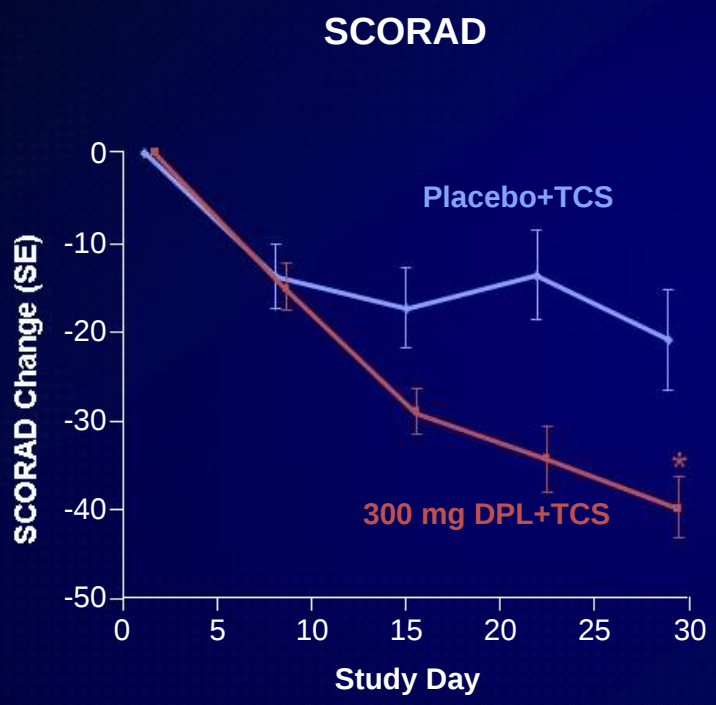
*p=0.0015



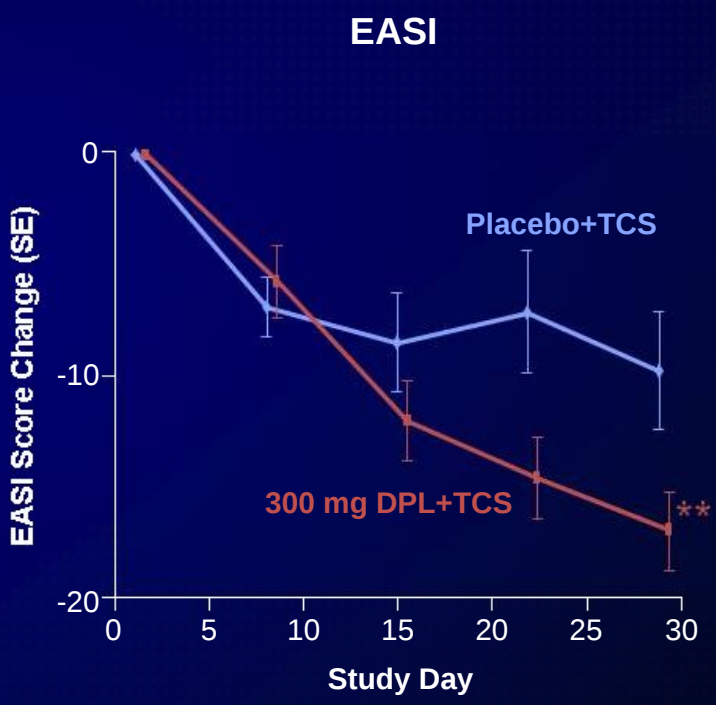
**p=0.0051

DPL=dupilumab
TCS=topical corticosteroids

Dupilumab+TCS significantly improved measures of efficacy vs TCS alone



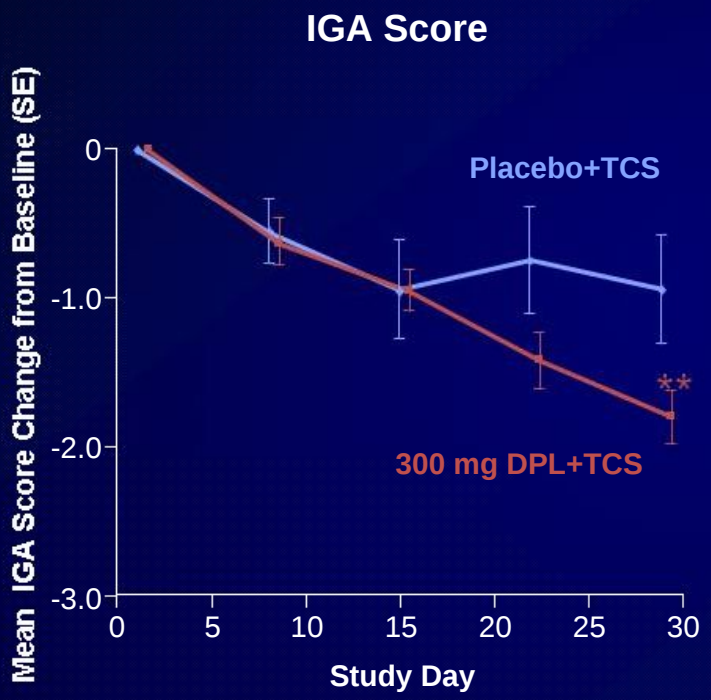
*p=0.0191



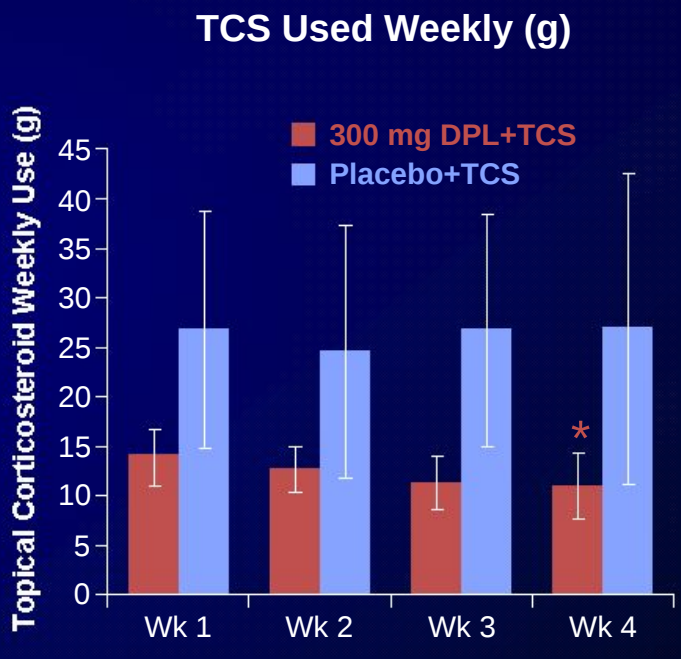
**p=0.0042

DPL=dupilumab
TCS=topical corticosteroids

Dupilumab+TCS achieved superior clinical outcomes vs TCS alone



**p=0.0281



*p=0.1413

DPL=dupilumab
TCS=topical corticosteroids

Summary

- In this study of adults with moderate-to-severe AD, concomitant treatment with SC dupilumab+TCS exhibited an acceptable safety profile (primary endpoint)
  - Most common treatment-emergent AEs were nasopharyngitis (23.8% vs 20% for placebo), headache and oropharyngeal pain (both14.3% vs 10% for placebo)
- At 4 weeks, dupilumab+TCS group achieved superior clinical outcomes compared to TCS alone (exploratory efficacy endpoints)
  - EASI-50: 100% responder rate for dupilumab +TCS, compared to 50% for placebo+TCS
  - Significantly better improvement from baseline in EASI, SCORAD, IGA, and pruritus NRS for dupilumab + TCS vs. Placebo + TCS
- Patients on dupilumab + TCS used approximately 50% less TCS during the treatment period compared with patients on placebo + TCS (48.7g vs 99.4g), associated with faster clearing of active AD lesions

Acknowledgements

All participating patients

Investigators

Diamant Thaci
Margitta Worm
Martin Kaatz
Rolf Dominicus
Beatrice Gerlach
Beate Schwarz
Noemi Bakos
Lajos Kemeny
Marcin Ambroziak
Maria Czubek
Maris Juszkiewicz-Borowiec
Andrzej Kaszuba
Dorota Bystrzanowska
Athanasios Tsianakas

Sanofi

Jennifer Cairns
Jeffrey Ming
Susan Slaytylak-Cheeks

Regeneron

Marius Ardeleanu
Elisa Babilonia
Nancee Basinger
Warren Brooks
Josh Cantor
Linda Williams
Tara Coughlan
Judy Cusick
Evelyn Dorsey
Kristen Dougherty
Chad Fish
Usman Chaudhry
Melissa Hager
Jennifer Hamilton
Rebecca Indibi
Richard Kao
Dan Kropas
Jacquie Kuritzky
Vicky Lai
Haobo Ren
Dawn Rich
Tara Seeliger

BACK UP

The march of atopic eczema