USE OF DUPILUMAB IN THE TREATMENT OF ATOPIC DERMATITIS IN REAL CLINICAL PRACTICE

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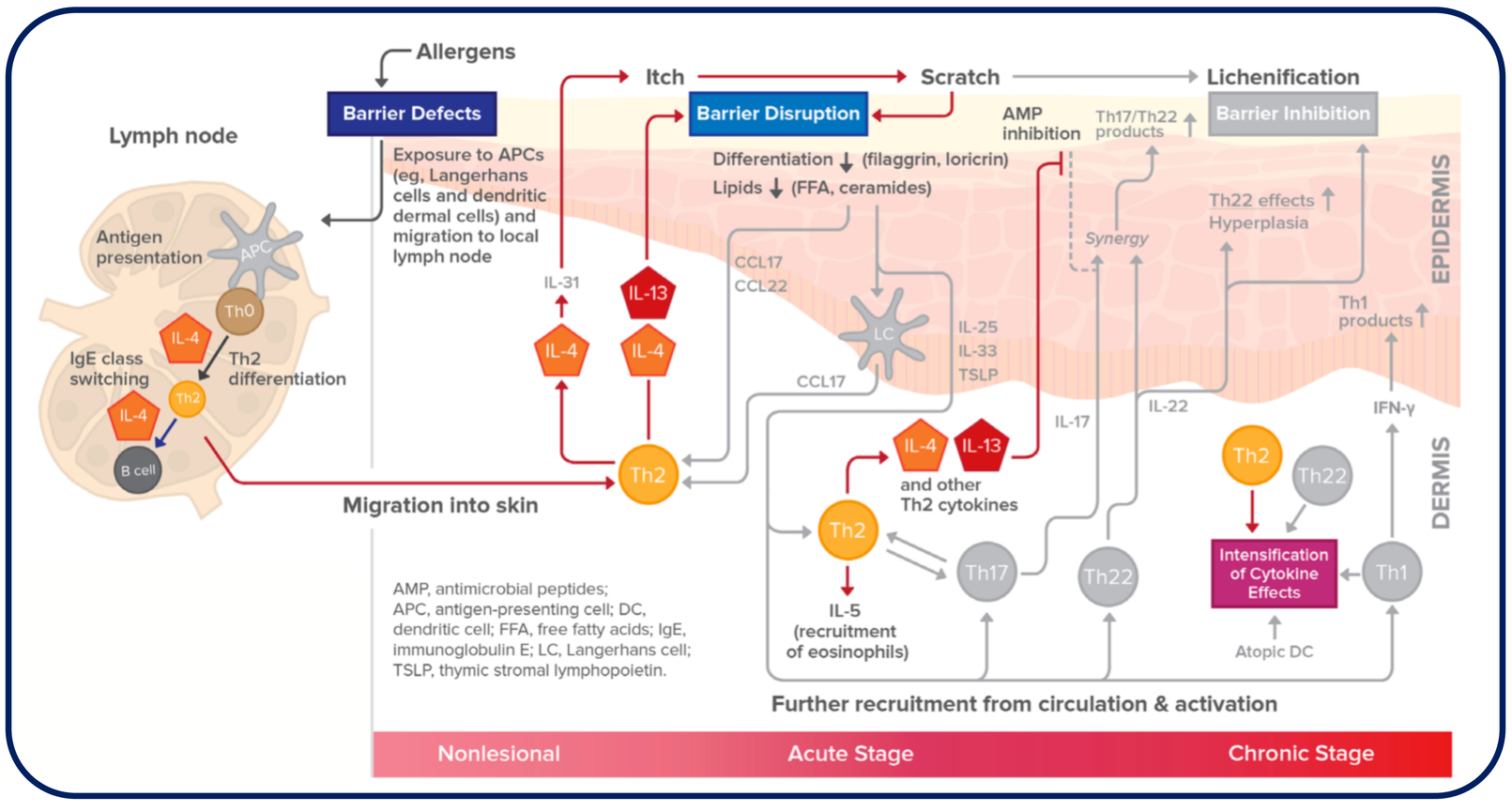
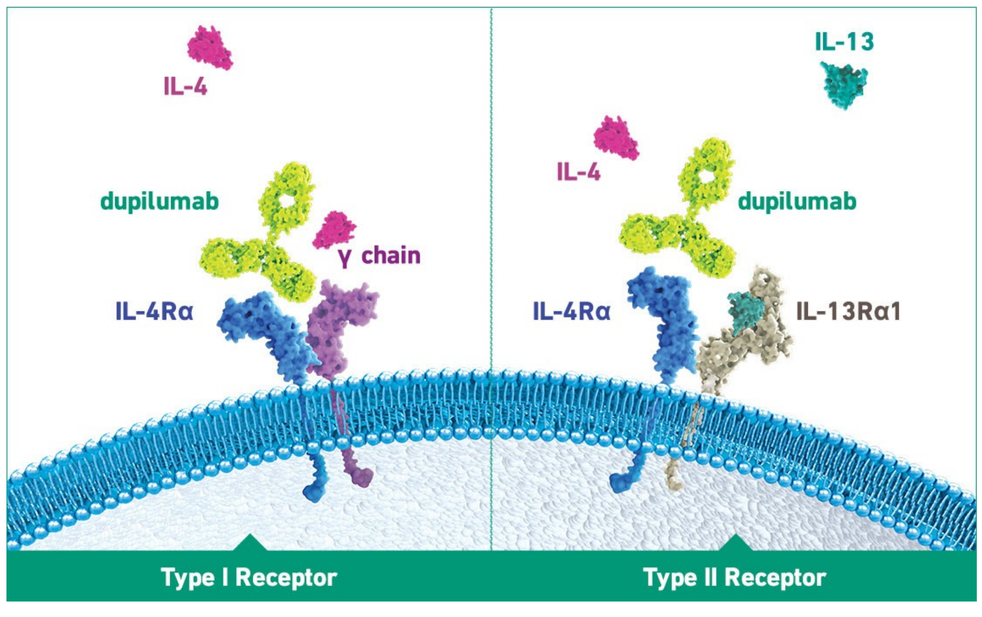
Background:

Atopic dermatitis (AD) is one of the most common cutaneous inflammatory diseases. Intense itching and rash can significantly compromise patient's life quality. The treatment of AD was based on topical/systemic non-specific anti-inflammatories drugs, immunosuppressants or phototherapy. In 2016 Italian marketing authority (AIFA) approved dupilumab for severe AD treatment. This monoclonal antibody inhibits the signal transduction of interleukin-4 and interleukin-13 implicated in the inflammatory cascade of the pathology.

Aim and objectives:

The purpose of this work is to describe dupilumab's use in real clinical practice and to compare its effectiveness with the marketing authorization trials.





Material and methods:

52 weeks efficacy and safety of dupilumab were evaluated in a randomized, double-blind, placebo-controlled clinical trials (LIBERTY_AD_CHRONOS). Disease index for patients enrolled in our structure (January-2019 to June-2020) were recorded inside an anonymous database built by matching administrative data and AIFA monitoring register. Chi-Squared test was used to show a statistically significant difference between clinical trial and real life.

Results:

166 patients were enrolled during the observed period: median age 43 (range 25-58), 58% males. At baseline: EASI median value was 28 (range 25-32), NRS 8 (range 8-9), DLQI 21 (range 15-25).After 52 weeks the patients with reassessment were 60. EASI median value 4 (range 2-7.8), NRS 2 (range 1-3), DLQI 3 (range 2-5). The average percentage reduction of EASI was -81.2% (Dev.St 21.3); NRS -69.9% (Dev.St. 27.0); DLQI -15.9% (Dev.St 7.5). A reduction of 75% in EASI value was recorded for 47 patients (78%).

Conclusion:

In our structure, patients with at least 75% EASI reduction were 47 (78%) compared to 58 (65%) in LIBERTY_AD_CHRONOS. EASI's average percentage reduction in our structure was -81.2±21.3 compared to trial's -78.4±4.4. Although the efficacy data seems to be different, Chi-Squared test showed that there isn't statistically significant difference between the trial and our reality (P>0.05). A full compliance with the eligibility criteria, also guaranteed by AIFA's monitoring database, confirm the efficacy of dupilumab also in real world medicine with therapy outcomes similar to the marketing authorization trial.

		Trial CHRONOS	AOUI - VR
		Dupilumab every other week	Dupilumab every other week
Parametro	Unità di misura	N° pazienti = 106	N° pazienti = 166
Age (Years)	Median + IQR	40,5 (28,0 - 49,0)	43,0 (25,0 - 58,0)
Gender (Male)	N° patients (%)	62 (58)	97 (58)
Duration of desease (Years)	Median + IQR	28,0 (20,0 - 44,0)	19,5 (6,0 - 30,0)
IGA > 4 (Investigators Global assesment)	N° patients (%)	53 (50)	NA
Eczema Area Severity Index	Median + IQR	30,9 (22,3 - 41,6)	28,0 (25,0 - 32,0)
Pruritus Numerical Rating Scale	Median + IQR	7,7 (6,6 - 8,5)	8,0 (8,0 - 9,0)
Dermatological Life Quality Index	Median + IQR	13,5 (8,0 - 20,0)	20,5 (15,0 - 25,0)

IQR = Interquartile range

Comparison between Trial CHRONOS and AOUI-VR baseline data

Observed Data

EASI 75% →	Reached	Not reached	TOT.
CHRONOS patients	58	31	89
AOUI-VR patients	47	13	60
TOT.	105	44	149

Null Hypothesis Data

EASI 75% →	Reached	Not reached	TOT.
CHRONOS patients	62,72	26,28	89
AOUI-VR patients	42,28	17,72	60
TOT.	105	44	149

Chi squared value	2,985
P value	0,084

References:

Blauvelt A et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY_AD_CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet. 06/10/2017;389(10086):2287-2303.

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