COST-EFFECTIVENESS ANALYSIS OF DUPILUMAB FOR THE TREATMENT OF SEVERE ATOPIC DERMATITIS IN ADOLESCENT AND CHILDREN PATIENTS IN ITALY

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BACKGROUND

- Atopic dermatitis (AD) is a chronic, multifactorial, inflammatory skin disease of unknown origin, with early onset and relapsing course, characterized by a significant impact on patients' quality of life [1,2].
- Recently, dupilumab has been reimbursed by Italian Medicines Agency (AIFA) for the treatment of adolescents (according to the AIFA registry criteria) and adults with severe AD.

OBJECTIVE

- The objective of this analysis was to estimate the incremental cost-effectiveness ratio (ICER) of dupilumab versus current supportive care (SC), for the treatment of severe AD in children (6-11 years) and adolescents (12-17 years), eligible for systemic therapy, for which treatment with topical medications is contraindicated, ineffective, or not tolerate, in Italy.

METHODS

- Simulation of outcomes and costs was undertaken using two sequential models: i) one initial 1-year decision tree, with 16-week and 52-week chance nodes, (**Figure 1a**), followed by: ii) a lifetime horizon Markov model (**Figure 1b**).
- The analysis was conducted on the overall population of the studies LIBERTY AD ADOL (NCT03054428) for adolescents [4] and LIBERTY AD PEDS (NCT03345914) [5] for children.
- The treatment response rate at 52 weeks was adjusted from the CHRONOS study [6]. New data has been published recently [7], but it was not considered as it was published after the conduction of the analysis.
- According to the Italian National Healthcare Service (NHS) perspective, only direct costs were captured.

RESULTS

Base-case analysis

- In the base-case, over lifetime horizon, dupilumab was more effective than SC, in both children and adolescent populations (+2.42 and +1.60 quality-adjusted life years -QALYs-respectively), **Table 1**.
- The introduction of dupilumab led to an increase in treatment costs (+€64,675 and +€52,578, respectively for children and adolescents), partially offset by a decrease in the costs of disease and complication management and an improvement in the quality of life (**Table 1**).
- The ICER were €21,462 per QALY gained, for the children, and €26,886 per QALY gained, for the adolescent population.

Sensitivity analysis

- One way sensitivity analysis (OWSA) confirmed the robustness of the analysis. The variability of the ICER was modest for both populations.
- The cost-effectiveness acceptability curve (CEAC) of the comparison between dupilumab and SC shows that when the willingness to pay (WTP) is equal to € 50,000 per QALY earned, dupilumab has 100 % chance of being cost-effective compared to supportive care, for both children and adolescents (**Figure 2** and **Figure 3**).

Figure 1. Model structure: Decision tree (a); Markov model (b)

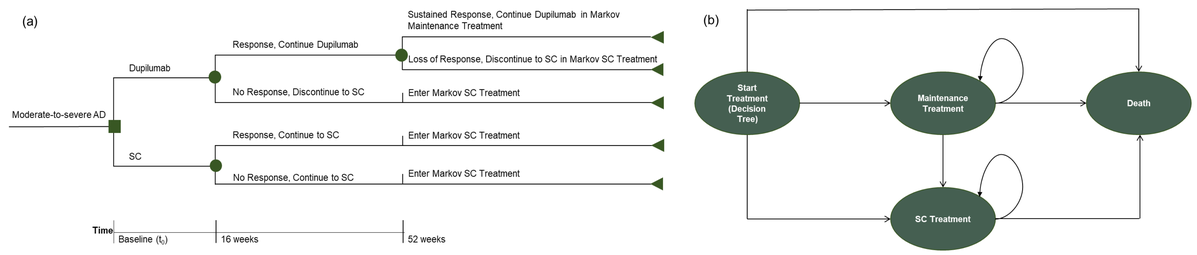

Figure 2. Acceptability curve: dupilumab vs supportive therapy (Adolescents)

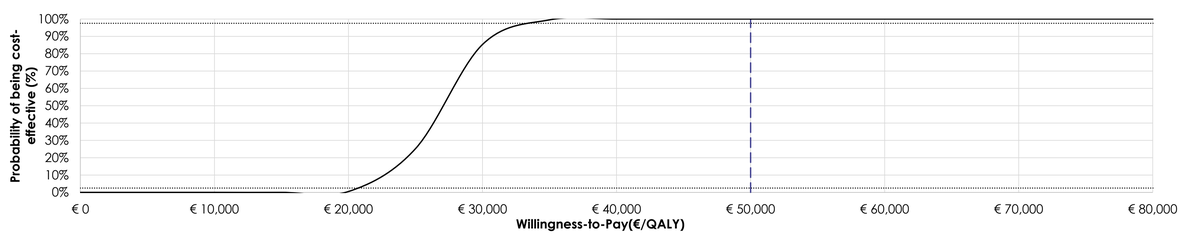

Figure 3. Acceptability curve: dupilumab vs supportive therapy (Children)

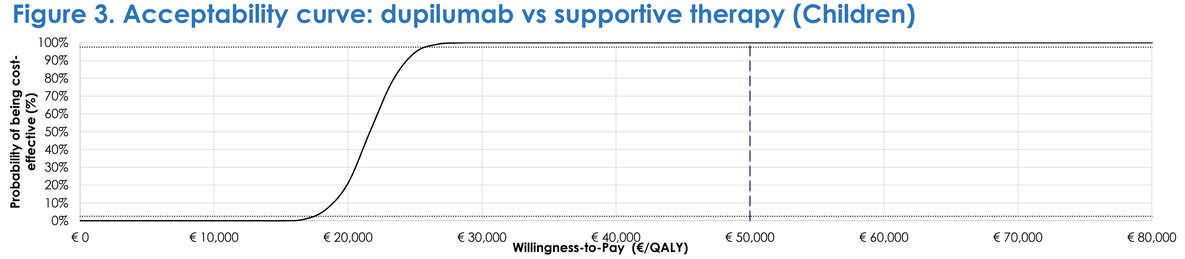

Table 1. Results of the base-case analysis

Population	Results	Dupilumab	Supportive care	Difference
Children	QALY	19.37	16.95	+2.42
	Total costs	€127,903	€76,038	€51,864
	ICER		**€ 21,462**	
Adolescents	QALY	18.23	16.64	+1.60
	Total costs	€118,000	€75,042	€42,958
	ICER		**€ 26,886**	

CONCLUSIONS

- The cost-utility showed that dupilumab is an effective therapeutic alternative to supportive care, in the treatment of adolescents and children with moderate to severe atopic dermatitis.
- The resulting ICERs are favorable and below the acceptability thresholds commonly used in Italy. Both sensitivity analyzes confirm that the therapeutic approach with dupilumab is "economically appropriate" and sustainable.

ACKNOWLEDGEMENTS AND DISCLOSURES

- This analysis was financially supported by Sanofi S.p.A (Milan, Italy).
- Pedone M., Serra A.: employees of Sanofi S.p.A.; Bitonti R. and Furneri G.: received consulting fees from Sanofi S.p.A. for analysis conduction and poster development.

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