COST-EFFECTIVENESS ANALYSIS OF DUPILUMAB FOR THE TREATMENT OF PRURIGO NODULARIS IN ADULT PATIENTS IN ITALY

Prada M,[1,2] Bertozzi C,[2] Fagnocchi G,[1] Aiello A,[1] Ronci G,[3] Cassini B,[3] Pedone MP.[3]

1) Intexo Società Benefit, Milano. 2) Intexo Società Benefit, Roma. 3) Sanofi S.p.A., Milan – Italy.

Background

- Prurigo nodularis (PN) is a chronic inflammatory skin disease characterized by intensely pruritic, hyperkeratotic papulonodular lesions that dramatically impairs patients' quality of life.[1-3]
- Epidemiological studies have determined PN to be characterized by type 2 inflammatory and other coexisting chronic conditions such as: chronic liver disease, HIV, and type 2 diabetes mellitus (DM), among other diseases, but the aetiological significance of the relationship is not known.[4-7] PN is also associated with a substantial individual economic burden, emphasizing the necessity of research on effective treatment options.[8]
- Therapies commonly used in the systemic management of PN (all off-label: topical corticosteroids, immunosuppressants, UV phototherapies) target symptoms only, produce no clinically meaningful effects, and are associated with numerous side effects.[2,3,9,10]
- Dupilumab, a fully human monoclonal antibody, has been recently approved by the European Medicines Agency (EMA) for the treatment of adults (above 18 years) with uncontrolled moderate to severe PN.[11] Results of the phase 3 trials PRIME and PRIME2 demonstrated clinically and statistically significant improvement in parameters related to the extent, intensity, and severity of the signs and symptoms of PN, as well as those related to the impact of the disease on patients' quality of life, in a significant proportion of treated patients.[12]

Objective

- This analysis aimed to estimate the Incremental Cost-Effectiveness Ratio (ICER) of dupilumab vs supportive care (SC): Mild/Moderate Topical corticosteroids, Topical calcineurin inhibitors, in the Italian adult population with PN.

Methods

- Simulation of outcomes and costs was conducted using a 1-year decision tree followed by a lifetime (30 years) horizon Markov model.
- Clinical data were derived from the two parallel phase 3 trials PRIME and PRIME 2.[11]
- The analysis was conducted adopting the Italian National Health Service (NHS) perspective, according to the Agenzia Italiana del Farmaco (AIFA) guidelines.[13]
- Analyses were conducted over a lifetime horizon, applying a discount rate of 3% for health outcomes and costs.[14]
- In the model, the following costs were considered: i) Drug acquisition costs; ii) Disease management costs; iii) Costs of adverse events.
- The cost of PN according to the therapy response was calculated using the activity-based costing methodology.[15]
- The healthcare resource consumption was estimated with the support of Italian clinical experts and valorized at the national tariffs.[16-18]
- Robustness of findings was tested using both deterministic univariate analysis (DSA) and probabilistic sensitivity analysis (PSA).[13] An acceptability threshold of 40,000 €/QALY was considered.[19]

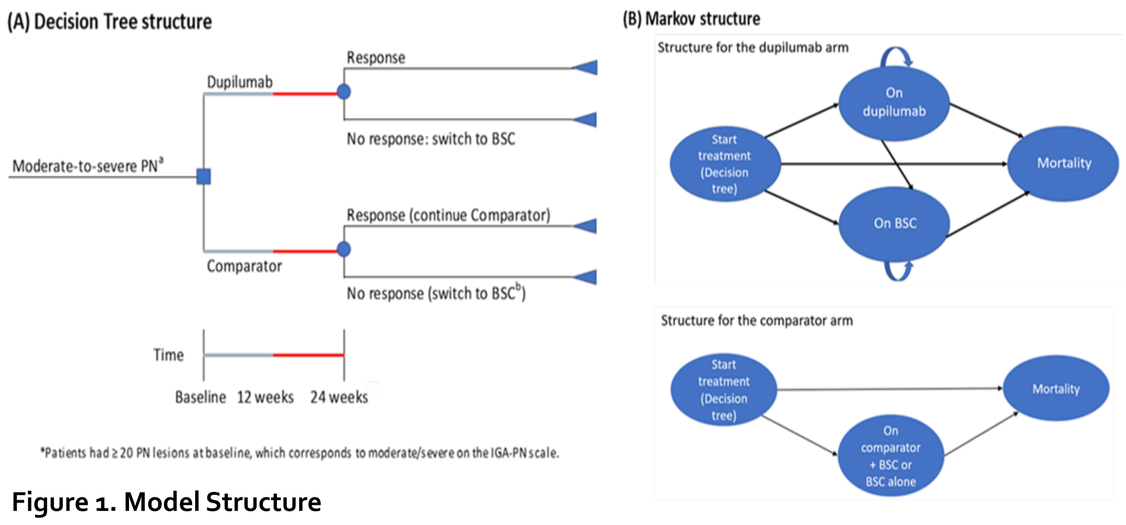

Figure 1. Model Structure

Results

- In the base-case, dupilumab was more effective than SC (+1.10 quality adjusted life years, QALYs).
- The introduction of dupilumab, at the currently reimbursed price, led to an increase in treatment costs (+€54,888), which are partially offset by a decrease in the costs of disease management and management of adverse events(respectively -€16,153 and -€183). The ICER vs SC was €34,991 per QALY gained, and fell below the ICER acceptability proposed for Italy (€ 40,000 per QALY gained).
- DSA confirms the robustness and reliability of base-case results. The variables that showed the greatest impact on outcomes were utility data both at baseline and associated with treatments.
- PSA developed on 1,000 simulations, estimated that in about 76% of them ICERs are below the acceptability threshold of 40,000 €/QALY.

	Therapy Cost (lifetime)	Healthcare Cost (lifetime)	Total Cost	QALYs	ICER
Dupilumab	€54,888	€46,203	€101,091	12.845	**34,991 €/QALY**
SC	€0	€62,539	€62,539	11.743	

Table 1. BaseCase – Cost-Effectiveness Results with lifetime time horizon

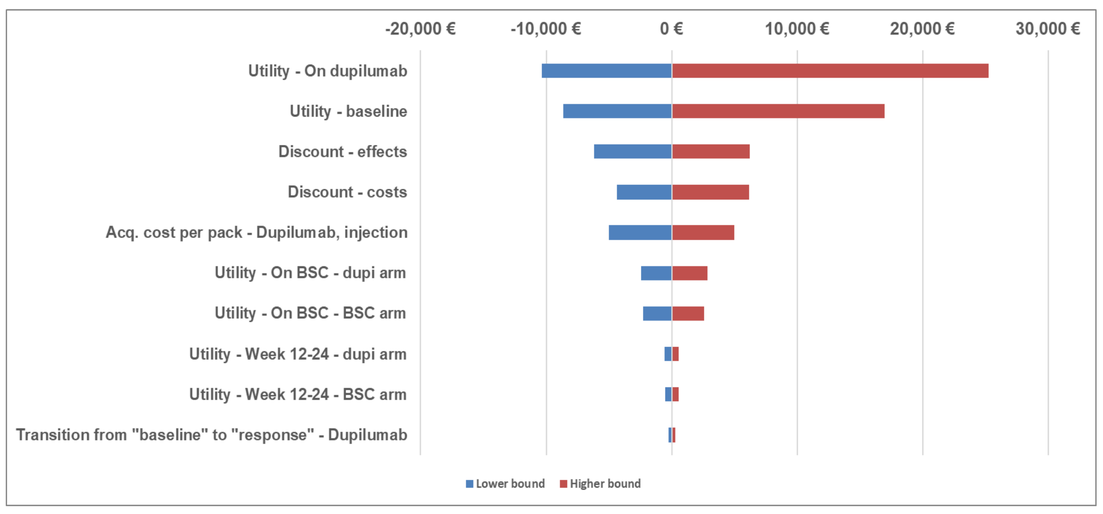

Figure 2. DSA – Tornado on the 10 Most Important Items

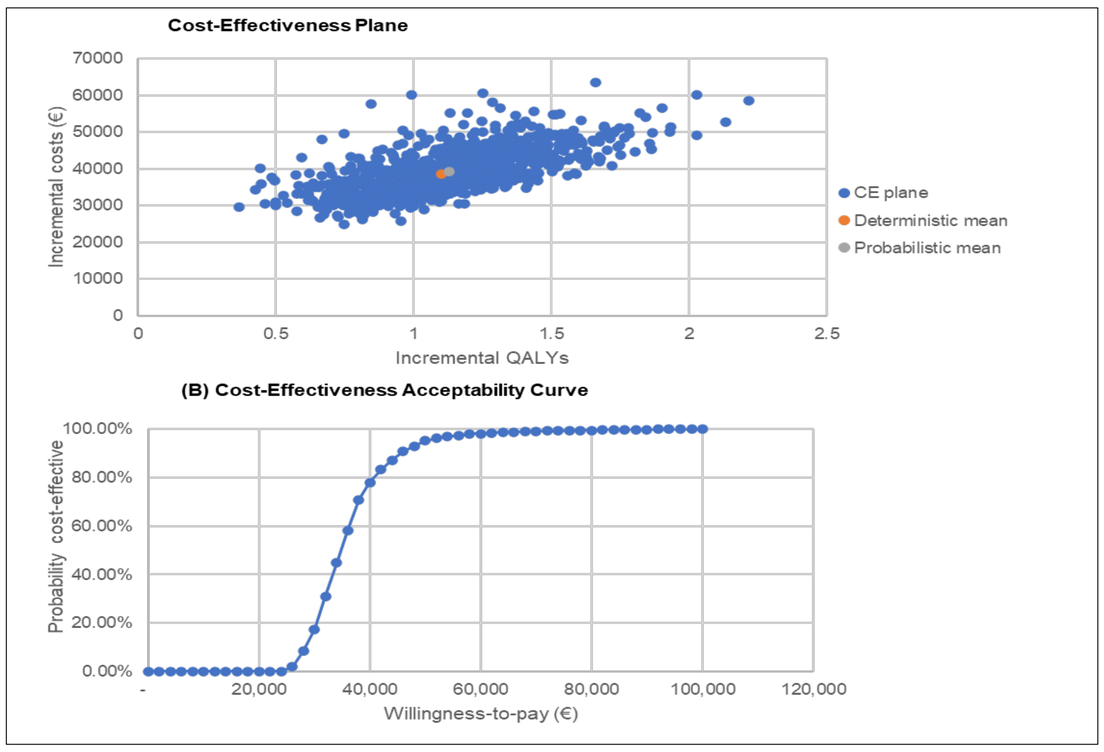

Figure 3. PSA – Cost-Effectiveness Plane & Acceptability Curve

Conclusions

- Dupilumab showed to be a cost-effective treatment for adults with uncontrolled moderate to severe PN in Italy, compared with SC, from the NHS perspective at the currently reimbursed cost.

Disclosure: Study funded by Sanofi S.p.A.

CONFLICTS OF INTEREST: AA, CB, GF and MP are employees of Intexo. GR, BC and MPP are employees of Sanofi and may hold stock/stock options in Sanofi.

References:

1. Janmohamed SR et al., Arch Dermatol Res. 2021 Oct;313(8):669-677 2. Pereira MP et al. J Eur Acad Dermatol Venereol. 2020 Oct;34(10):2373-2383. 3. Kowalsi EH et al. Clin Cosmet Investig Dermatol. 2019 Feb 28;12:163-172. 4. Huang AH, Williams KA et al., J Am Acad Dermatol 2020; 83: 1559–1565. 5. Augustin M et al., J Eur Acad Dermatol Venereol 2021; 35: 2270–2276. 6. Wikström K et al., Acta Derm Venereol 2021; 101: advo0508. 7. Huang AH et al., Invest Dermatol 2020; 140: 480–483.e4. 8. Whang KA et al. J Am Acad Dermatol. 2022 Mar;86(3):573-580 9. Pereira MP et al. J Eur Acad Dermatol Venereol. 2018 Jul;32(7):1059-65. 10. Zeidler C et al. Dermatol Clin. 2018 Jul;36(3):189–97. 11. https://www.ema.europa.eu/en/medicines/human/EPAR/dupixent 12. Yosipovitch G et al. Nat Med. 2023 May;29(5):1180-1190. 13. https://www.aifa.gov.it/documents/20142/1283800/Linee_guida_dossier_domanda_rimborsabilita.pdf 14. Fattore G et al, PharmacoEconomics – Italian Research Articles. 2009;11(2):83-93. 15. Baker J.J. Activity-Based Costing and Activity-Based Management for Healthcare. Gaithersburg (MD): Apen, 1998. 16. Ministero della Salute. Tariffario Nazionale Ambulatoriale. 2012. 17. Conferenza delle regioni e delle province autonome. Accordo interregionale per la compensazione della mobilità sanitaria. 2021. 18. Ministero della Salute. Progetto Mattoni SSN. 19. Fattore G. Pharmacoeconomics-Ital-Res-Articles. 2009;11:83–93.