# Abstract Coversheet

<table>
<thead>
<tr>
<th>Working title</th>
<th>A Bayesian network meta-analysis comparing the efficacy of dupilumab versus tralokinumab in adults with severe atopic dermatitis with inadequate response or intolerance to cyclosporin A</th>
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</thead>
<tbody>
<tr>
<td>Author(s)</td>
<td>Patricia Guyot¹, Boya Chandrasekhar², Andrea Chiricozzi³⁴, Ronci Gianluca⁵, Pedone Mariapaola⁵, Kerry Noonan⁶, Zhixiao Wang⁷</td>
</tr>
</tbody>
</table>
| Affiliations  | ¹Sanofi, Gentilly, Paris, France  
²Sanofi, Hyderabad, Telangana, India  
³UOC di Dermatologia, Dipartimento di Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli-IRCCS, Rome, Italy  
⁴Dermatologia, Dipartimento di Medicina e Chirurgia Traslazionale, Università Cattolica del Sacro Cuore, Rome, Italy  
⁵Sanofi S.p.A., 20158 Milan, Italy  
⁶Sanofi, Cambridge, MA, USA  
⁷Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA |
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**Inclusion of tables and figures**

May insert one (1) chart or graph.

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Abstract

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### Authors’ details:

<table>
<thead>
<tr>
<th>Author</th>
<th>Email ID</th>
<th>Complete mailing address (Institution name, city, state, country)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patricia Guyot</td>
<td><a href="mailto:patricia.guyot2@sanofi.com">patricia.guyot2@sanofi.com</a></td>
<td>Sanofi, Campus Sanofi Val de Bièvre, 94250 Gentilly, Paris, France</td>
</tr>
<tr>
<td>Boya Chandrasekhar</td>
<td><a href="mailto:boya.chandrasekhar@sanofi.com">boya.chandrasekhar@sanofi.com</a></td>
<td>Sanofi, Hyderabad, Telangana 500076, India</td>
</tr>
</tbody>
</table>
| Andrea Chiricozzi     | chiricozzia andre@gmail.com                    | UOC di Dermatologia, Dipartimento di Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli-IRCCS, 00168 Rome, Italy  
                        |                                                                                                              | Dermatologia, Dipartimento di Medicina e Chirurgia Traslazionale, Università Cattolica del Sacro Cuore, 00168 Rome, Italy |
| Ronci Gianluca        | gianluca.ronci@gmail.com                       | Sanofi S.p.A., 20158 Milano, Italy                                                                         |
| Pedone Mariapaola     | mariapaola.pedone@sanofi.com                  | Sanofi S.p.A., 20158 Milano, Italy                                                                         |
| Kerry Noonan          | kerry.noonan2@sanofi.com                      | Sanofi, Cambridge, MA 02141, USA                                                                           |
| Zhixiao Wang          | zhixiao.wang@regeneron.com                    | Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591, USA                                                   |
A Bayesian network meta-analysis comparing the efficacy of dupilumab versus tralokinumab in adults with severe atopic dermatitis with inadequate response or intolerance to cyclosporin A

Authors: Patricia Guyot, Boya Chandrasekhar, Andrea Chiricozzi, Ronci Gianluca, Pedone Mariapaola, Kerry Noonan, Zhixiao Wang

Affiliations: Sanofi, Gentilly, Paris, France; Sanofi, Hyderabad, Telangana, India; UOC di Dermatologia, Dipartimento di Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli-IRCCS, Rome, Italy; Dermatologia, Dipartimento di Medicina e Chirurgia Traslazionale, Università Cattolica del Sacro Cuore, Rome, Italy; Sanofi S.p.a., 20158 Milan, Italy; Sanofi, Cambridge, MA, USA; Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Abstract

Background: Cyclosporin A (CSA), approved in some countries in the European Union for treating severe AD, is associated with nephrotoxicity and hypertension that limit its long-term use. Biologic agents, such as dupilumab and tralokinumab, approved by the United States Food and Drug Administration for the treatment of uncontrolled moderate-to-severe AD, are associated with consistent symptomatic improvement over long-term use, either with or without concomitant topical corticosteroids (TCS).

Objectives: To evaluate the efficacy of dupilumab/TCS vs tralokinumab/TCS using placebo/TCS as a common comparator in adult patients with AD with
inadequate response to CSA or for whom CSA treatment was medically
inadvisable.

**Methods:** LIBERTY AD CAFÉ (NCT02755649) and a subgroup of LIBERTY AD
CHRONOS (NCT02260986; inadequate response/medically inadvisable to CSA)
were pooled. This pooled data (CAFÉ + CAFÉ-CHRONOS-LIKE [CCL]) comparing
dupilumab/TCS vs placebo/TCS and ECZTRA 7 (NCT03761537) clinical trial
comparing tralokinumab/TCS vs placebo/TCS were included in the network
meta-analysis (NMA). Difference in mean change from baseline (CFB) for
Eczema Area and Severity Index (EASI) score, Peak Pruritus Numeric Rating
Scale (PP-NRS), and odds of achieving EASI 50, EASI 75, EASI 90, ≥ 4-point
improvement in PP-NRS and Investigator’s Global Assessment of clear/almost
clear skin score (IGA 0/1) were the efficacy endpoints included in the analysis.
Mean difference in CFB in the Dermatology Life Quality Index (DLQI) was also
included as a quality-of-life endpoint. Dichotomous endpoints were expressed as
odds ratio (OR). The number needed to treat (NNT) for achieving dichotomous
endpoints were computed to compare treatment benefits. Continuous outcomes
were expressed as difference in mean CFB. All the endpoints were assessed at
Week 16. An indirect treatment comparison was performed using the WinBugs
software to perform Bayesian NMA with fixed effects model method using 95%
credible interval (CrI).

**Results:** A total of 576 patients (ECZTRA: placebo: 137; tralokinumab: 140;
CCL: placebo: 169; dupilumab: 130) were included in the NMA. Improvement in
EASI, PP-NRS and DLQI measured by mean difference in CFB was significantly
higher for dupilumab/TCS, compared to tralokinumab/TCS at week 16 (mean
difference in CFB for EASI [− 9.46 {95% credible interval, CrI: − 13.37, −
5.54}]; PP-NRS: − 0.87; [− 1.67, − 0.07], and DLQI: − 3.38; [− 5.20, − 1.56].
Compared to placebo/TCS, the odds for achieving EASI 50 (OR: 4.68; [2.15, 10.43]), EASI 75 (OR: 2.92; [1.46, 5.87]), EASI 90 (OR: 4.81; [2.18, 10.93]), ≥ 4-point improvement in PP-NRS (OR: 3.45; [1.62, 7.48]), and IGA 0/1 (OR: 2.60; [1.19, 5.79]) were also significantly higher with dupilumab/TCS vs tralokinumab/TCS. The NNT was lower with dupilumab/TCS vs tralokinumab/TCS for achieving EASI 50 (3 vs 8), EASI 75 (3 vs 7), EASI 90 (3 vs 12), ≥ 4-point improvement in PP-NRS (3 vs 12) and IGA 0/1 (3 vs 9).

**Conclusions:** This NMA suggests that treatment with dupilumab/TCS was associated with significant improvements in EASI, PP-NRS, DLQI, and IGA in comparison with tralokinumab/TCS. Dupilumab/TCS was also associated with lower NNT than tralokinumab/TCS, making it a valuable therapy in patients with severe AD.

**Keywords:** Moderate-to-severe atopic dermatitis, Biologic agents, Network meta-analysis, Head-to-head comparisons, Long-term use

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