

Safety and Effectiveness of Dupilumab in the Treatment of Atopic Dermatitis in Japanese Patients: The First Interim Analysis Report From Post-Marketing Surveillance

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Background and Methods: Dupilumab is a human anti-IL-4 receptor α chain (IL-4R α) monoclonal antibody that has been used in Japan since April 2018 for the treatment of atopic dermatitis (AD) in adult patients with inadequate responses to existing treatment. To better understand the safety and effectiveness of dupilumab in the real world, this study reported the results of an interim analysis based on data from 231 patients collected and fixed by March 2020.

Results: The mean (standard deviation [SD]) age of the patients analyzed was 42.0 (15.6) years, and duration of treatment was 24.6 (14.5) weeks. Adverse reactions were observed in 44 (19.1%) patients, in which 21 (9.1%) conjunctivitis patients, 13 (5.6%) allergic conjunctivitis patients, and 3 (1.3%) blepharitis patients were reported. A case of pyoderma was observed as a serious adverse reaction with an outcome of recovery. 38 patients discontinued administration of the drug; the main reasons were the improvement of AD (9 patients), economic issues (7 patients), adverse events (3 patients), and lack of sufficient effectiveness (2 patients).

Conclusion: The rate of adverse reactions to dupilumab administration in adults with AD in the real world did not exceed that in clinical trials up to the time of approval (33.9%), and so far, there have been no specific safety concerns.

Acknowledgements

Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifiers: UMIN-CTR Trials Registry: UMIN000032807. Medical writing/editorial assistance was provided by Amy O'Callaghan, PhD, of Excerpta Medica, and was funded by Sanofi Genzyme and Regeneron Pharmaceuticals, Inc., according to the [Good Publication Practice guideline](#).

Disclosures

Fujita H, Suzuki K, Arima K: Sanofi K.K. – employees, may hold stock and/or stock options in the company.