COVID-19 in tralokinumab-treated patients with moderate-to-severe atopic dermatitis: case series from the ECZTEND long-term extension trial

Andrew Blauvelt¹, Andrew Pink², Margitta Worm³, Richard Langley⁴, Antonio Costanzo⁵, Le Gjerum⁶, Emilie Jorgensen⁶, Joshua Corriveau⁷, Emma Guttmann-Yassky⁸

¹Oregon Medical Research Center, Portland, OR, USA
²St. John’s Institute of Dermatology, Guy’s and St. Thomas’ Hospitals, London, UK;
³Division of Allergy and Immunology, Department of Dermatology, Venereology and Allergy, Charité –Universitätsmedizin Berlin, Berlin, Germany
⁴Division of Clinical Dermatology and Cutaneous Science, Dalhousie University, Halifax, NS, Canada;
⁵Dermatology Unit Department of Biomedical Sciences, Humanitas University, Via Rita Levi Montalcini, 20089, Pieve Emanuele, Milano, Italy. Skin Pathology Laboratory, Humanitas Research Hospital IRCCS, Via Manzoni 56, 20089, Rozzano, Milano, Italy
⁶LEO Pharma A/S, Ballerup, Denmark
⁷LEO Pharma Inc., Madison, NJ, USA
⁸Department of Dermatology and the Immunology Institute, Icahn School of Medicine at Mount Sinai, New York, NY, USA

Introduction
There is special interest in the impact of coronavirus disease 2019 (COVID-19) on individuals with chronic immune-mediated diseases such as atopic dermatitis (AD). There have been concerns that patients treated with immunomodulatory therapies for these diseases may have increased risk of developing COVID-19 or more severe disease with worse outcomes following infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Tralokinumab is a fully human immunoglobulin G4 monoclonal antibody that specifically binds with high affinity to IL-13 and prevents its interaction with the IL-13 receptor, thereby inhibiting subsequent downstream signalling and improving AD, a type 2-mediated disease. The objective of this case series is to describe the outcomes of patients diagnosed with COVID-19 while participating in the tralokinumab long term extension trial, ECZTEND (NCT 03587805).

Methods
Approximately 1600 patients with moderate-to-severe AD across Canada, the United States, Europe, and Japan are participating in the ongoing open-label ECZTEND study. Here, we report a case series of 51 adult patients with moderate-to-severe AD who had confirmed cases of COVID-19 during treatment with tralokinumab every 2 weeks. Patients were not required to discontinue tralokinumab treatment following a COVID-19 diagnosis, if continuation was deemed appropriate by the investigator. This is an interim analysis of data collected through February 26, 2021.
Results
 Twenty-two male and 29 female patients were diagnosed with COVID-19 through February 2021. The mean age was 37.7 years (range 19-70 years) and the mean BMI was 27.6 (range 16.3-50.8). Regarding comorbidities that confer additional risk of severe COVID-19, 59% (n/N, 30/51) of patients had asthma and 10% (5/51) had hypertension; cardiovascular disease was present in 2 patients and chronic obstructive pulmonary disease (COPD) and diabetes mellitus were present in 1 patient each.

COVID-19 severity was predominantly mild (35/51, 68.6%) or moderate (14/51, 27.5%), and all patients with mild or moderate disease recovered fully. The two patients who experienced severe cases (2/51, 3.9%) had multiple risk factors and comorbidities, including obesity, COPD, and cardiovascular disease. Both were hospitalized and subsequently recovered (one with sequelae); neither case was reported as related to tralokinumab treatment. Mean duration of infection was 15 days (range 1-39 days). Only two of the 51 COVID-19 cases were reported as possibly related to tralokinumab treatment; both were mild or moderate cases occurring in patients under the age of 30.

All (51/51) patients continued tralokinumab treatment, the majority (38/51, 75%) without dose interruptions following COVID-19 diagnosis. In the ECZTEND study, 19 patients have received the first dose of COVID-19 vaccine and 6 patients have received the second dose; no patients had adverse events leading to permanent discontinuation based on data collected through February 26, 2021.

Discussion
 Severe COVID-19 is characterized by release of pro-inflammatory cytokines, leading to pulmonary inflammation and impairment of lung function. IL-13 is not thought to be a major contributor to host defense mechanisms against viral infections. The recent ECZTRA 5 vaccine study showed that non-live vaccines could be safely administered and can elicit normal immune responses in patients treated with tralokinumab.¹ In the present study, COVID-19 cases were predominately mild or moderate (96%), and all patients continued tralokinumab treatment following COVID-19 diagnosis.

References:
 1. Merola J, et al. Tralokinumab does not impact vaccine-induced immune responses: results from a 30-week, randomized, placebo-controlled trial in adults with moderate-to-severe atopic dermatitis. J Am Acad Dermatol. 2021. Published online 17 March 2021. Doi: 10.1016/j.jaad.2021.03.032
Disclosures:

Andrew Blauvelt is a scientific adviser and clinical study investigator for AbbVie, Aclaris, Almirall, Arena, Athenex, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Dermira, Eli Lilly, FLX Bio, Forte, Galderma, Janssen, LEO Pharma, Novartis, Ortho Derm, Pfizer, Regeneron Pharmaceuticals, Inc., Sandoz, Sanofi Genzyme, Sun Pharma, UCB Pharma, and a paid speaker for AbbVie.

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