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

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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. In the present study, COVID-19 cases were predominately mild or moderate (96%), and all patients continued tralokinumab treatment following COVID-19 diagnosis.

References:
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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Antonio Costanzo has served on advisory boards Celgene, UCB, Eli Lilly, Pfizer, Janssen, Novartis, Sanofi-Genzyme and MSD.

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