**Introduction**

- There is special interest in the impact of COVID-19 on individuals with chronic immune-mediated diseases such as atopic dermatitis (AD), including concerns that patients treated with immunosuppressive therapies for these diseases may have increased risk of developing COVID-19 or more severe disease with worse outcomes following infection.
- AD is a chronic inflammatory disease, characterized by exacerbations of skin lesions and multiple symptoms, including pruritus, sleep disruption, and depression.
- Tralokinumab is a high-affinity, fully-human, monoclonal antibody designed to specifically neutralize interleukin-31 (IL-31), a key driver of the underlying inflammation in AD.
- Phase 3 trials have established the efficacy and safety of tralokinumab for up to 52 weeks in adult patients with moderate-to-severe AD.
- An ongoing, open-label extension trial, ECZTEND (NCT03518905), is investigating the long-term safety and efficacy of tralokinumab in patients with AD who participated in previous tralokinumab trials.

**Objective**

- To describe the outcomes of adult patients diagnosed with COVID-19 while participating in the tralokinumab long-term extension trial, ECZTEND.

**Methods**

- As shown in Figure 1, ECZTEND is an ongoing, 5-year, open-label, single-arm, multicenter, long-term extension trial in adult patients with AD who participated in parent tralokinumab trials (ECZTRA 1-8 and TrOject).
- Approximately 1500 patients with moderate-to-severe AD across Canada, the United States, Europe, and Japan are participating in ECZTEND.
- Patients received subcutaneous tralokinumab 300 mg every 2 weeks plus optional TCS after 300 mg or 650 mg loading dose of tralokinumab.
- Safety follow-up 6 weeks after last investigational medicinal product (IMP).
- Key inclusion criteria for ECZTEND:
  - Completed treatment period(s) in a tralokinumab parent trial (ECZTRA 1-8 or TrOject)
  - No safety concerns.
  - Completed with the clinical trial protocol in the parent trial.
  - Able and willing to self-administer tralokinumab, or have it administered by a caregiver, at home after the initial 3 injection visits at trial site.
  - Applied a stable dose of maximal (minimum two doses) for at least 45 days before baseline.
- Here, we report a case series of 31 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**

**Patient characteristics**

- Twenty-two male and 29 female patients were diagnosed with COVID-19 through February (Table 1).
- The mean age was 37.7 years (range 19-70 years) and the mean BMI was 27.6 (range 16.3-50.8).

**Table 1.** Baseline demographics for patients in ECZTEND with confirmed cases of COVID-19.

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Male, n (%)</th>
<th>Female, n (%)</th>
<th>BMI, mean (range)</th>
<th>Geographic region North America, n (%)</th>
<th>Europe, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.7 (7-90)</td>
<td>22 (63%)</td>
<td>29 (94%)</td>
<td></td>
<td>27.6 (16.3-50.8)</td>
<td>15 (50%)</td>
<td>36 (117%)</td>
</tr>
</tbody>
</table>

**Table 2.** Clinical characteristics for patients in ECZTEND with confirmed cases of COVID-19.

<table>
<thead>
<tr>
<th>COVID-19 Case Series (N=31)</th>
<th>Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease duration in days</td>
<td>15.2 (3-66)</td>
</tr>
<tr>
<td>Intensive course Mild, n (%)</td>
<td>55 (69%)</td>
</tr>
<tr>
<td>Moderate, n (%)</td>
<td>16 (27%)</td>
</tr>
<tr>
<td>Severe, n (%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td></td>
</tr>
<tr>
<td>Mean duration of stay (range)</td>
<td>7 (3-15)</td>
</tr>
<tr>
<td>Possible related to treatment n (%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Recovery</td>
<td></td>
</tr>
<tr>
<td>Total, n (%)</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>No dose interruption, n (%)</td>
<td>38 (75%)</td>
</tr>
<tr>
<td>Dose interruption, n (%)</td>
<td>13 (25%)</td>
</tr>
</tbody>
</table>

**Table 3.** Adverse events details for patients in ECZTEND with confirmed cases of COVID-19.

**Relevance of COVID-19 to AD**

- COVID-19 is a viral disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- It is primarily a respiratory illness, but it can cause damage to many other organs.
- Patients with severe COVID-19 can have complications such as pneumonia, shock, kidney failure, and respiratory failure.
- Patients who have severe COVID-19 may need to be hospitalized, put on ventilators, or given other treatments to help them breathe.
- COVID-19 can also cause complications such as heart disease, stroke, or diabetes.
- Patients who recover from COVID-19 may have lasting effects such as fatigue, shortness of breath, or muscle weakness.

**Conclusions**

- In the present study, patients with moderate-to-severe AD treated with tralokinumab did not experience adverse events leading to permanent discontinuation after receiving the vaccine as per data cut-off.

**Disclosures**

- All authors provided a statement of interest.
- A full list of authors is provided in the original publication.
- No potential conflicts of interest were reported by the authors.

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**Acknowledgements**

- The ECZTEND trial was sponsored by UCB Pharma.
- Editorial support was provided by Claire Gaye, PhD of Alphapharm Health (New York, NY), supported by UCB Pharma, according to Good Publication Practice guidelines.

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**Original paper:**