COVID-19 in atopic dermatitis: a case series from the ECTRA®-N-E-T registry and a long-term extension trial (ECZTEND)

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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 immunomodulatory agents for these diseases may have increased risk of developing COVID-19 or more severe disease with worse outcomes following infection.1,2

AD is a chronic inflammatory disease,3 characterized by eczematous skin lesions and multiple symptoms, including pruritus, sleep disturbance, and depression.4,5

Tralokinumab is a high-affinity, fully human, monoclonal antibody designed to bind specifically to interleukin-13 (IL-13), a key driver of the underlying inflammation in AD.6

Phase 3 trials have established the efficacy and safety of tralokinumab for up to 29 weeks in adult patients with moderate to severe AD.7

An ongoing, open-label extension trial, ECTRA®-N-E-T (NCT03587805), is exploring the long-term safety and efficacy of tralokinumab in adult 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, ECTRA®-N-E-T.

Methods

As shown in Figure 1, ECTRA®-N-E-T is an ongoing, 5-year, open-label, single-arm, multicenter, long-term extension trial in adult patients with AD who participated in previous tralokinumab trials (ECTRA®-I and Tridaq).8

- Approximately 1,600 patients with moderate to severe AD across Canada, the United States, Europe, and Japan are participating in ECTRA®-N-E-T.

- Patients received subcutaneous tralokinumab 300 mg Q4W or TCS use plus TCS after a 300 mg or 650 mg loading dose of tralokinumab.

- Safety follow-up is 16 weeks after last investigational medicinal product administration.

- Major inclusion criteria for ECTRA®-N-E-T:
  - Completed treatment period(s) in a tralokinumab patient trial (ECTRA®-I or Tridaq) without any safety concerns.
  - Complied with the clinical trial protocol in the parent trial.
  - Able and willing to self-administer tralokinumab, or if he administered by a caregiver, at home after the initial 3 injection visits at trial site.
  - Applied a stable dose of eucerline (minimum twice daily) for at least 14 days before baseline.

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

Patient characteristics

- Twenty-two male and 29 female patients were diagnosed with COVID-19 through February 26, 2021 (Table 1).

- The mean age was 57.7 years (range 19-70) and the mean BMI was 27.6 (range 18.3-35.0).

- Comorbidities included hypertension, diabetes, cardiovascular disease, and respiratory disease.

- Baseline characteristics are included in Table 1.

COVID-19 exposure

- COVID-19 exposure was defined as patients with confirmed cases of COVID-19.

- The majority of patients were hospitalized for a median of 14 days (range 1-39).

- No patients required mechanical ventilation or intensive care unit admission.

- No patients had severe COVID-19.

- Table 2 includes clinical characteristics of patients with COVID-19.

Table 1. Baseline demographics for patients in COVID-19 case series.

<table>
<thead>
<tr>
<th>COVID-19 Case Series (n=51)</th>
<th>Disease duration in days (mean)</th>
<th>Disease duration in days (range)</th>
<th>Disease duration in days (median)</th>
<th>Disease duration in days (Q1-Q3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n=22)</td>
<td>5.6 (3.9-8.1)</td>
<td>3.9 (1.0-7.0)</td>
<td>3.9</td>
<td>3.0 (2.0-5.0)</td>
</tr>
<tr>
<td>Female (n=29)</td>
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Table 2. Clinical characteristics for patients in COVID-19 case series.

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Table 3. Adverse events details for patients in COVID-19 case series.

- In the ECTRA®-N-E-T study, 19 patients have received the first dose of COVID-19 vaccine and 4 patients have received the second dose; no patients have had adverse events leading to permanent discontinuation after receiving the vaccine as per data cut-off.

Concluding Remarks

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

- Severe COVID-19 is characterized by release of pro-inflammatory cytokines, leading to organ impairment and death.

- IL-15 is not thought to be a major contributor to host defense mechanisms against viral infection.

The recent ECTRA®-N-E-T vaccine study showed that non-live vaccines could be safely administered and did not elicit immune responses in patients treated with tralokinumab.9

References


Disclosures

- Andrew Blauvelt is a scientific advisor and clinical trial investigator for AbbVie, Actavis, Amgen, Ablynx, Boehringer Ingelheim, Biocodex, GSK, Galderma, Genentech, Janssen, Johnson and Johnson, Kyowa Kirin, LEO Pharma, Merz, Pfizer, Regeneron, Sanofi, and a paid speaker for AbbVie.

- Andrew Piné reports personal fees and nonfinancial support from LEO Pharma, Novartis, and UCB, and personal fees from AbbVie, Amgen, Roche, and LEO Pharma.

- Margittra Wom has served on advisory boards Celgene, AbbVie, Biogen, Genentech, Janssen, Merck, Merck KGaA, Pfizer, Regeneron, Sanofi, and a paid speaker for AbbVie.

- Richard Langley has served and received compensation in the form of grant funding and honoraria for scientific investigator for and on the scientific advisory board or as a speaker for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Janssen, LEO Pharma, Pfizer, Roche, and UCB, and is a paid consultant for AbbVie.

- Antonio Costanzo has served on advisory boards Celgene, UCB, Eli Lilly, Pfizer, Janssen, Novartis, and AbbVie.

- Lo Gjurea, Emilie Jorgensen, and Joshuva Cornell are employees of LEO Pharma A/S.

- Emma Guttman-Yassky has served on advisory boards AbbVie, Celgene, Janssen, Merck, Merck KGaA, Pfizer, Roche, and UCB, and has received personal fees from AbbVie, Amgen, and Janssen.

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