



Press Release

Update on U.S. FDA review of LEO Pharma's Biologics License Application for tralokinumab for the treatment of adults with moderate-to-severe atopic dermatitis

- FDA has requested additional data relating to a device component of tralokinumab
- FDA did not request additional data on the clinical efficacy or safety of the drug product formulation of tralokinumab
- LEO Pharma is working closely with FDA to support the approval of tralokinumab to bring this potential treatment option to U.S. adults living with moderate to severe atopic dermatitis

BALLERUP, Denmark, and MADISON, NJ, APRIL 29, 2021 – LEO Pharma A/S, a global leader in medical dermatology, today announced that the U.S. Food and Drug Administration (FDA) as part of their review of the company's Biologics License Application (BLA) for tralokinumab, an investigational therapy for adults with moderate-to-severe atopic dermatitis, has issued a Complete Response Letter requesting additional data relating to a device component of tralokinumab. FDA did not request any new data on the clinical efficacy or safety of the drug product formulation of tralokinumab.

"We are committed to bringing tralokinumab to the market to support the millions of U.S. adults who live with uncontrolled moderate-to-severe atopic dermatitis. The FDA has not raised any questions to the clinical efficacy or safety of tralokinumab, but only requested additional data relating to a device component of the combination product. We will now work closely with the FDA to address their request and bring tralokinumab to the U.S. patients as quickly as possible." said Jörg Möller, Executive Vice President, Global Research and Development at LEO Pharma.

The BLA submission was based on efficacy and safety results from the ECZTRA 1, 2 and ECZTRA 3 pivotal Phase 3 trials, which included more than 1,900 adult patients with moderate-to-severe atopic dermatitis. Safety data was evaluated from a pool of five randomized, double-blind, placebo-controlled trials, including ECZTRA 1, 2 and ECZTRA 3, a dose-finding trial, and a vaccine response trial.¹

LEO Pharma received a positive opinion for tralokinumab from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on April 22, 2021.

About atopic dermatitis

Atopic dermatitis is a chronic, inflammatory, skin disease characterized by intense itch and eczematous lesions.¹ Atopic dermatitis is the result of skin barrier dysfunction and immune dysregulation, leading to chronic inflammation.² Type 2 cytokines, including IL-13, play a central role in the key aspects of atopic dermatitis pathophysiology.³

About tralokinumab

Tralokinumab is the first fully human, monoclonal antibody developed to specifically neutralize the IL-13 cytokine, which plays a key role in driving the underlying atopic dermatitis signs and symptoms.^{3,4}

Tralokinumab specifically binds to the IL-13 cytokine with high affinity, thereby inhibiting interaction with the IL-13 receptor α 1-subunit of the type 2 receptor.^{3,4}

About LEO Pharma

LEO Pharma helps people achieve healthy skin. The company is a leader in medical dermatology with a robust R&D pipeline, a wide range of therapies and a pioneering spirit. Founded in 1908 and owned by the LEO Foundation, LEO Pharma has devoted decades of research and development to advance the science of dermatology, setting new standards of care for people with skin conditions. LEO Pharma is headquartered in Denmark with a global team of 6,000 people, serving 93 million patients in 130 countries. In 2020, the company generated net sales of DKK 10,133 million. For more information, please visit www.LEO-Pharma.com.

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References

1. Weidinger S, et al. Atopic dermatitis. *Lancet*. 2016; 387:1109-1122.
2. Boguniewicz M, et al. Atopic dermatitis: a disease of altered skin barrier and immune dysregulation. *Immunol Rev* 2011;242(1):233-46.
3. Bieber T. Interleukin-13: Targeting an underestimated cytokine in atopic dermatitis. *Allergy*. 2020; 75:54-62
4. Popovic B, *et al*. Structural characterisation reveals mechanism of IL-13-neutralising monoclonal antibody tralokinumab as inhibition of binding to IL-13R α 1 and IL-13R α 2. *J Mol Biol*. 2017; 429:208-19.

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