

# AQILION

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## Press release

## Aqilion receives IND approval from FDA

**AQILION AB (publ) today announces that the US Food and Drug Administration (FDA) has approved Aqilion's IND (investigational *new drug*) application for the drug candidate AQ280. The first study in the US aims to verify the pharmacokinetic profile of a new formulation of AQ280 specifically developed for the treatment of patients with EoE ("eosinophilic esophagitis").**

The purpose of this study (ARIA-2) is to ensure that the new formulation, a tablet that dissolves in water, has a similar pharmacokinetic profile to the capsule containing the drug candidate used in the Phase 1 study (ARIA-1). The ARIA-2 study is expected to be conducted in June in the US in healthy study participants and the results are expected after the summer. Aqilion then intends to submit an application to conduct a Phase 2 study in patients diagnosed with EoE in the US, Canada and Europe.

"It is strategically important for us to continue clinical development with a formulation that is specially adapted for patients who have difficulty swallowing. With a positive response from the FDA, we look forward to completing the final preparations for the start of a Phase 2 study in EoE patients", says Sarah Fredriksson, CEO of Aqilion.

### **For more information, please contact:**

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### **About the AQ280**

AQ280 is an oral, small-molecule, super selective JAK1 inhibitor. JAK1 is an enzyme, a kinase, that accelerates inflammatory processes, which, among other things effects allergy and fibrosis. By inhibiting its mechanism, it is possible to reduce symptoms and disease development in chronic inflammatory diseases.

### **About Eosinofil Esophagitis**

Eosinophilic Esophagitis is an allergic disease of the esophagus. The main symptom of this chronic disease is significant difficulty swallowing, and the disease can lead to scar tissue development and strictures of the esophagus causing food to get stuck or impact the esophagus. The disease can occur in patients of any age and it usually debuts at the age of 20-40. There is a clear medical need for new therapies as the number of patients diagnosed is rapidly increasing and the knowledge and awareness of the disease becomes more widespread. Currently, two different types of drugs have been approved: treatment with corticosteroids is approved in Europe and treatment with a biologic drug, an anti-IL4/13 antibody, is approved in the US and in Europe. There is currently no approved treatment of eosinophilic esophagitis with the same mechanism of action as Aqilion's drug candidate AQ280.

### **The ARIA-1-study**

The Phase 1 study was a randomized, double-blind, placebo-controlled study in healthy volunteers conducted in the United Kingdom to assess the safety, tolerability, pharmacokinetics,

and food efficacy of AQ280 dosed orally. The study consisted of both single and multiple ascending dose cohorts and included 66 healthy volunteers.

The main results from the ARIA-1 study are:

1. Dose: The exposures achieved in the Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) cohorts are in line with estimates of a therapeutically effective range based on preclinical models and will inform the dose selection for the upcoming Phase 2 study
2. Safety: No serious adverse events occurred and dose increases in SAD and MAD were not limited by adverse events
3. Pharmacokinetics: The exposure and half-life of AQ280 were consistent with the preclinical predictions and support once daily dosing. Food intake did not significantly affect pharmacokinetics
4. Pharmacodynamics: AQ280 inhibited CXCL10 in a dose-dependent manner. CXCL10 is an established biomarker for JAK inhibition
5. Selectivity: The JAK1 effects were evident and dose-related while no detectable JAK 2 effect on reticuloocytes could be detected

### **About Aqilion**

Aqilion is a Swedish biopharma company that develops innovative new therapies for diseases caused by chronic inflammation and dysfunctional immune reactions.

The company is mainly active in the idea stage to early clinical development. The goal is to demonstrate the clinical and commercial potential of the medical innovation to attract industrial partners and buyers, who in turn have the capacity to continue clinical development and take the drug to the patients.

Aqilion runs its development programs in a partly virtual organization in close collaboration with selected partners with specific expertise in drug development.

AQILION AB (publ) is a Swedish public limited company headquartered in Helsingborg, Sweden.

[www.aqilion.com](http://www.aqilion.com)