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Press release

Aqilion finalizes the eosinophilic esophagitis specific formulation pharmacokinetic study with the drug candidate AQ280

Aqilion AB is pleased to announce the completion of its second Phase 1 clinical study (ARIA-2) in the United States, as part of the AQ280 development program. The ARIA-2 study evaluated the pharmacokinetic profile of a novel, water-dissolvable tablet formulation of AQ280, designed for the treatment of eosinophilic esophagitis (EoE). The final participant has completed the study, and results are expected in October.

EoE patients have difficulties swallowing and oral therapies need to be adapted to facilitate their drug intake. Aqilion have developed a formulation that allows the EoE patients to drink the medicine like water.

The primary objective of ARIA-2 was to determine whether the new formulation exhibits a pharmacokinetic profile comparable to the capsule used in the initial Phase 1 study (ARIA-1). The study was conducted in June with healthy participants in the USA and the results are expected in October. Thereafter Aqilion plans to initiate a Phase 2 (a and b) clinical trials in patients diagnosed with EoE across the US, Canada, and Europe.

Sarah Fredriksson, CEO of Aqilion, stated, "We have completed the clinical part of the pharmacokinetic study with our new AQ280 formulation, which is an important milestone. Developing a formulation tailored for patients with difficulty swallowing is strategically extremely important. We thank the participants and clinic involved and look forward to advancing AQ280's clinical development."

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. AQ280 was well tolerated in the Aria-1 phase 1 study, and showed promising effects on relevant biomarkers.

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 and treatment with a biologic drug, an anti-IL4/13 antibody. 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 participants 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 reticulocytes 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.

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