AQILION

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Press release

Positive Results from Clinical Pharmacokinetic Study for the Eosinophilic Esophagitis Specific Formulation with the Drug Candidate AQ280

Aqilion today announces positive results from the ARIA-2 clinical study. The study evaluated the pharmacokinetic profile in healthy participants of a novel, water-dissolvable tablet formulation of AQ280, designed for the treatment of eosinophilic esophagitis (EoE) to enable phase 2. The ARIA-2 study was performed as a single-dose randomized, placebo controlled, cross-over study and expanded the dose range compared to the dose range used in Phase 1 (ARIA-1). The results clearly showed that the new formulation exhibits a pharmacokinetic profile very similar to the capsule used in the initial ARIA-1 study, with favorable safety and tolerability profile. The study results enable a transition to phase 2 with a formulation that is specifically adapted to patients with swallowing difficulties.

The hallmark of EoE is that patients have serious difficulties in swallowing and often food impaction, and therefore oral therapies need to be designed to facilitate drug intake. Aqilion has developed a formulation that allows EoE patients to take the medication dissolved in 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 in healthy participants in the US following an IND approval in May. The ARIA-1 study showed dose dependent changes in biomarkers suggestive of a potent JAK1 inhibitory effect while no detectable JAK 2 effect on reticulocytes was observed. Aqilion is now preparing to initiate Phase 2a and 2b clinical trials in patients diagnosed with EoE across the US, Canada, and Europe.

Sarah Fredriksson, CEO of Aqilion, stated, "We are pleased to see the results from this pharmacokinetic bridging study. It is an important milestone to have the formulation ready with EoE patients in focus. Finalizing ARIA-2 now means that we can fully focus on the Phase 2 study. 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 orally available, 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 Eosinophilic 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 were:
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-and time-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 was observed

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.
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