AQILION

Helsingborg October 30, 2023

Press release

Aqilion reports positive results from the ARIA-1 Phase 1 study in healthy subjects

- The drug candidate AQ280, an oral selective JAK1 inhibitor, was well tolerated, and the achieved single and multidose exposure is in line with estimates of a therapeutically effective range based on preclinical models
- Pharmacokinetic data supports once daily dosing
- Pharmacodynamic biomarker changes are consistent with JAK1 inhibition with no observed signs of JAK2 inhibition at the achieved exposures

AQILION (publ) reports positive results from its Phase 1 study ARIA-1 in healthy volunteers with the drug candidate AQ280, a selective proprietary JAK1 inhibitor, being developed as a treatment for eosinophilic esophagitis (EoE) within the Regulus program.

Healthy subjects were administered single or multiple doses in a sequential escalating dosing schedule until the maximum planned dose of AQ280 was reached. Data describing the pharmacokinetic profile, safety and pharmacodynamic biomarkers of the drug candidate have now been unblinded and evaluated.

Key findings from the ARIA-1 study are:

- Dose: The achieved exposures in the Single Ascending Dose (SAD)- and the 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 trial
- Safety: There were no serious adverse events and the dose escalations in SAD and MAD were not restricted by adverse events
- Pharmacokinetics: The exposure and half-life for AQ280 were well aligned with the preclinical predictions and supports once daily dosing. Food intake did not influence the pharmacokinetics in any significant way
- Pharmacodynamics: AQ280 inhibited CXCL10 in a dose-dependent manner. CXCL10 is a well-recognized biomarker for JAK inhibition
- Selectivity: The JAK1 on-target effects were evident, and dose related, and there was only minimal effects on reticulocyte values, a marker of JAK2 inhibition.

"These results represent the first clinical data with our drug candidate AQ280 and it is a valuable milestone both in the Regulus program and for Aqilion. We are very pleased with the results, and taken together these data encourages us to progress our preparations for Phase 2 in patients with eosinophilic esophagitis", says Sarah Fredriksson, CEO Aqilion.

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About the AQ280
AQ280 is an oral, small molecule, selective JAK1 inhibitor. JAK1 is an enzyme, a kinase, that accelerates inflammatory processes, which, among other things effects allergy and fibrosis. By

inhibiting its function, it is possible to reduce symptoms and disease development in chronic inflammatory diseases.

The ARIA-1 study
The Phase 1 study was a randomized, double-blind, and placebo-controlled study in healthy subjects conducted in the UK to assess the safety, tolerability, pharmacokinetics, and food effect of AQ280 dosed orally. The study consisted of both single-and multiple-ascending dose cohorts and enrolled 66 healthy subjects. Doses studied in the study ranged from 3 mg to 60 mg in a once daily regimen.

About Eosinophilic Esophagitis
Eosinophilic Esophagitis is an allergic disease of the esophagus. The main symptom of this chronic disease is severe difficulty swallowing, and the disease can lead to scar tissue development and strictures of the esophagus causing food to get stuck or impacted in the esophagus. The disease can occur in patients of any age but tends to be more common in younger adults. There is a clear medical need for new therapies as the incidence is rapidly increasing. In addition the fact that more patients are diagnosed as the knowledge and awareness of the disease becomes more widespread the number of patients is growing rapidly and has not yet reached a plateau. 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.

About Aqilion
Aqilion is a Swedish biotech company developing innovative treatments for diseases caused by chronic inflammation and dysfunctional immune reactions.

The company is mainly active in early phases of drug discovery, taking ideas 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 commercialization.

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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