AQILION

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Press release

Aqilion starts Phase 1 clinical trial with drug candidate AQ280 for chronic inflammatory diseases

AQILION AB (publ) announces today that the Phase 1 clinical safety study on the drug candidate AQ280 on healthy volunteers has started. The substance AQ280, part of the company's Regulus development program, is a super selective JAK1 small molecule inhibitor that is under development for indications within chronic inflammatory diseases. Aqilion has thus reached a very important milestone as the company has managed to take the big step from preclinical phase to clinical Phase 1.

The Phase 1 clinical trial, ARIA-1, will include 64 healthy volunteers. The purpose of the study is to investigate possible side effects and pharmacokinetics (how the body breaks down and gets rid of the substance). ARIA-1 is being conducted as a dose escalation study, which means that the trial begins with a very low dose, after which the dose is gradually increased. The primary aim of the study is to determine the tolerability and safety of AQ280, which will be evaluated in steps in one group with an escalating single dose (single ascending dose, SAD) and in another group with a repeated oral dosage over several days (multiple ascending dose, MAD). The clinical trial is being conducted in the UK with the approval of the British Medicines and Healthcare Products Regulatory Agency (MHRA). The results from the Phase 1 clinical trial are expected in the mid-2023.

The aim of the Regulus program is to develop a next-generation JAK1 inhibitor. Drugs with a similar mechanism of action have demonstrated clinical efficacy in autoimmune and inflammatory diseases. Aqilion will initially test, assess, and develop the drug candidate AQ280 as a potential treatment for eosinophilic esophagitis (EoE), an inflammatory disease of the esophagus, that is also known as "allergic esophagitis". Once the Phase 1 clinical trial is completed, Aqilion intends to apply for drug testing prior to the Phase 2a study in patients. To date, no drugs with this mechanism of action has been developed for EoE and there is a large and growing unmet medical need.

"Our first Phase 1 clinical trial has begun, which means that Aqilion is now a biopharmaceutical company that engages in clinical development. Taking the step from preclinical to clinical development is an incredibly important milestone for everyone involved. So far, development in the Regulus program and of the drug candidate AQ280 has been highly effective thanks to a small, unique, talented, and highly experienced team that together represent one of Aqilion's greatest strengths," says Sarah Fredriksson, CEO of Aqilion. "Moreover, I am both proud and pleased that we have also succeeded in establishing a pipeline with an innovative profile and a clear focus within chronic inflammatory diseases, including programs from discovery to early clinical development."

For more information, please contact:
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About eosinophilic esophagitis
Eosinophilic esophagitis (EoE) is a rare chronic disease involving inflammation of the esophageal mucosa; its main symptom among patients is swallowing difficulties. EoE is a relatively new diagnosis that is increasing in incidence. The disease, also known as "allergic esophagitis," is triggered by food allergens and characterized by a progressive course with a risk of strictures in the esophagus. Both children and adults can be affected and the diagnosis is most common in children in their teens and in adults aged 30-50. The condition is more common in men.

About Aqilion's pipeline
Aqilion has four programs in various phases of development in its pipeline. All programs focus on developing novel innovative treatments for chronic inflammatory diseases for which few or no treatments are available and where there is currently a clear patient need.

The Regulus program's AQ280, a selective JAK1 inhibitor, is initially being developed as a potential treatment for EoE and a Phase 1 safety study is ongoing. The Girtab program was developed in-house and Aqilion owns all intellectual property rights. The aim of the Girtab program is to develop a new treatment for chronic inflammatory bowel disease (IBD). The preclinical Alnitak program is developing an oral medication that specifically binds to and inhibits the TAK1 (MAP3K7) target protein, which has been shown to serve as a master regulator of inflammatory signaling. The program has been expanded and resources are also being invested in a project that focuses specifically on substances with the potential to treat inflammatory conditions of the central nervous system (CNS). The Polaris program has a new pharmacological strategy for selectively modulating NLRP3 inflammasome signaling and has the potential to be first in its class with a novel mechanism of action. Polaris is in the early research phase. More information is available on the website at pipeline.

About Aqilion
Aqilion is a biotech company that focuses on developing new innovative treatments for diseases caused by chronic inflammation and dysfunctional immune reactions such as autoimmune diseases. The company is mainly active in the early phases of drug discovery, from idea to early clinical development.

Aqilion combines its experience from major pharmaceutical companies with the drive and entrepreneurship of small growth companies. With solid experience in business development in innovative biotech and pharmaceutical companies, the company's experienced team and Board of Directors have successfully navigated the process from drug discovery to market.

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