AQILION

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Press release

Aqilion receives regulatory approval to conduct Phase 1 clinical trial in Regulus program within inflammatory diseases

Aqilion is announcing today that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has approved the company's Phase 1 clinical trial with its drug candidate AQ280.

Aqilion applied to conduct a Phase I safety study in 64 healthy volunteers with the drug candidate AQ280 within the Regulus program. The study, ARIA-1, will be conducted in the UK. The purpose of the study is to investigate possible side effects and pharmacokinetics (how the body breaks down and gets rid of the substance). The study will be conducted as a dose escalation study by beginning with a very low dose and then gradually increasing the dose. ARIA-1 is planned to start in August and results are expected in the second quarter of 2023. The goal for the drug candidate AQ280 is to test it and initially evaluate it as a potential treatment for eosinophilic esophagitis (EoE), an inflammatory disease of the esophagus.

"The Phase I clinical trial in the Regulus program is an important milestone for Aqilion, as we take the step from preclinical to clinical development. I am proud that we have effectively prepared and completed the application for the clinical study with AQ280 in such a short time. This has been our top priority since we acquired all rights to Regulus in December 2021. We want to optimally manage the high-quality work that LEO Pharma invested in the project by quickly initiating the first clinical safety study, followed by a Phase IIa study in patients," says Sarah Fredriksson, CEO of AQILION.

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 is swallowing difficulties. EoE is a relatively new diagnosis that is increasing in incidence. The disease, which has a progressive course, is also known as "allergic esophagitis" and is thought to be triggered by food allergens. 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 (AQ280) is initially being developed as a potential treatment for EoE and a Phase I safety study is about to start. 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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